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# **Disease, Morality and Bioethics**

## **An Ethnographic Study of a TB Vaccine Trial Site in South Africa**

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**May 2017**



**Title:** Disease, Morality and Bioethics: An Ethnographic Study of a TB Vaccine Trial Site in South Africa

**Author:** Justin A Dixon

This thesis offers an ethnographic account of the work of a research institute called the South African Tuberculosis Vaccines Initiative (SATVI), which has been running tuberculosis (TB) vaccine trials in the Western Cape since 2001. The chapters show that SATVI has become deeply embedded in the local socioeconomic and healthcare landscape through the ground-level conduct of its vaccine trials. However, the significance of the trials in people's lives goes beyond providing access to resources against the backdrop of withdrawing state structures. The focus is on how the trials have become entangled in people's attempts to craft lives that they consider to be valuable, moral and respectable in conditions that have been rendered precarious by centuries of racialised domination, control and stereotyping.

The thesis firstly shows that the post-apartheid health system has retained residues of authoritarianism through the democratic transition and that TB control focuses attention upon individual behaviour and lifestyles through the neoliberal language of 'responsibility'. Against this backdrop, SATVI's trials generated novel relationships and possibilities gravitating around the pursuit of the 'greater good' of a new TB vaccine and the bioethical ideal of the autonomous, rights-bearing 'human subject'. Within these research relationships, participants not only felt valued, respected and included. Participants and research staff also engaged with health and wellbeing in ways that contest the common perception in the government clinics that residents are unwilling or unable to 'take responsibly' in matters of personal and community health. What emerges from this thesis is a moral economy surrounding trial participation that, firstly, challenges the bioethical construction of 'vulnerability'. Secondly, it unsettles a tendency in social science research to emphasise the material dimensions of trial participation at the expense of a broader spectrum of imperatives and subject positions from which people approach and interpret medical science.

# **Disease, Morality and Bioethics**

## **An Ethnographic Study of a TB Vaccine Trial Site in South Africa**

Justin Alexander Dixon

Thesis Submitted for the Degree of Doctor of Philosophy

Department of Anthropology

Durham University

2017

# Table of Contents

<b>Chapter 1: Introduction .....</b>	<b>11</b>
Globalised Clinical Trials .....	21
Neoliberalism and Global Health.....	25
The Interface Between ‘Global’ and ‘Local’ .....	28
Respectability in Post-Apartheid South Africa .....	33
TB, Morality and the Human Subject .....	36
The Chapters .....	43
<b>Chapter 2: Field Site and Study Design .....</b>	<b>47</b>
SATVI and Post-Apartheid Worcester .....	47
Study Design .....	51
(i) Participant Observation .....	54
(ii) Interviews .....	55
Ethical Considerations .....	57
(i) Harms and Benefits .....	59
(ii) Informed Consent .....	60
(iii) Privacy and Confidentiality.....	61
<b>Chapter 3: “We Learned Research by Actually Doing It”: A History of SATVI...63</b>	
A Meeting of ‘Local’ and ‘Global’ Agendas .....	67
Networks and Relationships.....	70
SATVI’s First Community Advisory Board .....	73
Staffing and GCP Training.....	75
Trial and Error.....	78
(i) Informed Consent .....	79
(ii) The Case Verification Ward.....	81
(iii) Taking the Nurse out of the Nurse .....	82
Developments Since the BCG Trial.....	85
(i) Phase I and IIa Trials.....	86
(ii) Other Preparatory Studies .....	88
(iii) Site Development .....	89
(iv) The Trial of MVA85A .....	95
Conclusions .....	96

<b>Chapter 4: A Disease beyond Reach: Clinic Staff Perspectives on the Past and Present of TB Control.....</b>	<b>99</b>
A Shifting Primary Healthcare Landscape.....	103
The TB Rooms .....	109
“It’s the Ones that are Out There” .....	111
Nurses and TB Discourse.....	116
(i) Isolation and Accountability .....	117
(ii) Responsibility and Blame .....	120
(iii) Nostalgia for the Past .....	124
Conclusion .....	126
<b>Chapter 5: “We Treat them as Special”: The Social Dynamics of Recruitment in Post-Apartheid Worcester.....</b>	<b>129</b>
Fieldwork in a Post-Apartheid Setting.....	131
Fieldworkers and Community Life .....	134
The Closures of Affluence .....	136
Avalanche Sampling and Gang Territories .....	140
‘Reimbursements’ and the Unemployed.....	145
Spaces and Relations of Consent .....	148
Filling in the Forms.....	154
Conclusion .....	156
<b>Chapter 6: Truth, Blood and Respectability: Trial Participation and the Embodiment of ‘Clean’ Blood .....</b>	<b>159</b>
A Note on Quotations .....	164
TB and ‘Dirt’ .....	164
“In my Life it is not Money that is Important, it is...” .....	169
‘Looking’ Beyond What You ‘See’ .....	173
Donations of ‘Clean Blood’ .....	177
Trials as Moral Triage.....	182
Conclusion .....	188
<b>Chapter 7: “We are not Dominating Them”: Comparisons and Connections Between SATVI and the Government Clinics.....</b>	<b>191</b>
Perceptions of Care in Research Settings.....	194
Health Checks and Blood Screenings .....	196
Access and Clinic Environments .....	198
Hierarchy and Communication .....	202

Diagnostics and Follow-Up.....	210
Referral into the Health System .....	215
Conclusion .....	217
<b>Chapter 8: “We Don’t Treat We Refer”: Sovereign Responsibility and the Transition from Participant to Patient .....</b>	<b>220</b>
Partnerships with Healthcare Facilities .....	224
Refer not Treat, Advise not Prescribe .....	227
Clinic Staff Perceptions of SATVI .....	232
Community Presence and Active Case Finding .....	236
Post-Referral Management of Patients.....	242
Conclusion .....	247
<b>Conclusion: Rethinking Carina’s Choice .....</b>	<b>251</b>
TB, Gangsters and Nurses.....	252
Carina’s ‘Brave Choice’ .....	255
From Misconceptions to Moral Economy .....	257
The Limits of Hope .....	260
Shifting Markets and Future Research.....	263
<b>Appendix 1: Carina’s Choice .....</b>	<b>265</b>
<b>Appendix 2: The Rhythms of Study Visits.....</b>	<b>275</b>
<b>Appendix 3: Socioeconomic Indicators and Social Grants .....</b>	<b>278</b>
<b>Appendix 4: Informed Consent Forms .....</b>	<b>280</b>
<b>Bibliography .....</b>	<b>290</b>

# List of Tables

Table 1	Shorthand used to describe participant demographics	164
Table 2	Breakdown of participant motivations n (%) across trials	169

# List of Figures

Figure 1	SATVI's project office or "the Boiler House"	48
Figure 2	SATVI's recruitment hotspots	50
Figure 3	The Trials House (Outside)	90
Figure 4	The Trials House (Inside)	90
Figure 5	The ACS Building (Outside)	92
Figure 6	The ACS Building (Inside)	92
Figure 7	The Vaccine Trials Clinic	93
Figure 8	The Vaccine Trials Clinic (Waiting Area)	94
Figure 9	Worcester Community Day Centre	100
Figure 10	The TB Department	101
Figure 11	Roodewal Flats	143
Figure 12	Two separate teams of fieldworkers coincidentally arrive at the same block of flats in Riverview	143
Figure 13	Typical SATVI Referral Letter	229



# Abbreviations and Key Acronyms

SATVI	The South African Tuberculosis Vaccines Initiative
TB	Tuberculosis
MDR-TB	Multi-drug-resistant tuberculosis
XDR-TB	Extensively-drug-resistant tuberculosis
BCG Vaccine	Bacillus Calmette-Guérin Vaccine
GCP	Good Clinical Practice
DOTS	Directly-Observed Treatment, Short Course
WHO	World Health Organisation

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**For Alec Dixon**

# Chapter 1

## Introduction

I would like to begin with the story of Carina, a fictional young woman who lives in the Breede Valley of the Western Cape, South Africa. In this story, Carina makes a ‘brave choice’ to enrol her baby, Cookie, in a TB vaccine trial run by the South African Tuberculosis Vaccines Initiative (SATVI). SATVI is a research institute that has been conducting TB vaccine research in the Breede Valley since 2001 and has involved over 20,000 infants, adolescents and adults in its research over the years (Hanekom et al. 2012). The story of Carina was presented in a comic called *Carina’s Choice* (see Appendix 1), which was used as an educational tool in the build-up to an early efficacy trial involving nearly 3,000 infants between 2009 and 2012. It starts at the Kleynhans’ family home with Carina and her brother, Trevor (nicknamed Tupac). Tupac is a school-age teenager, but frequently skips school to cause mischief with his ‘crew’. For the last few weeks, he has been coughing a lot:

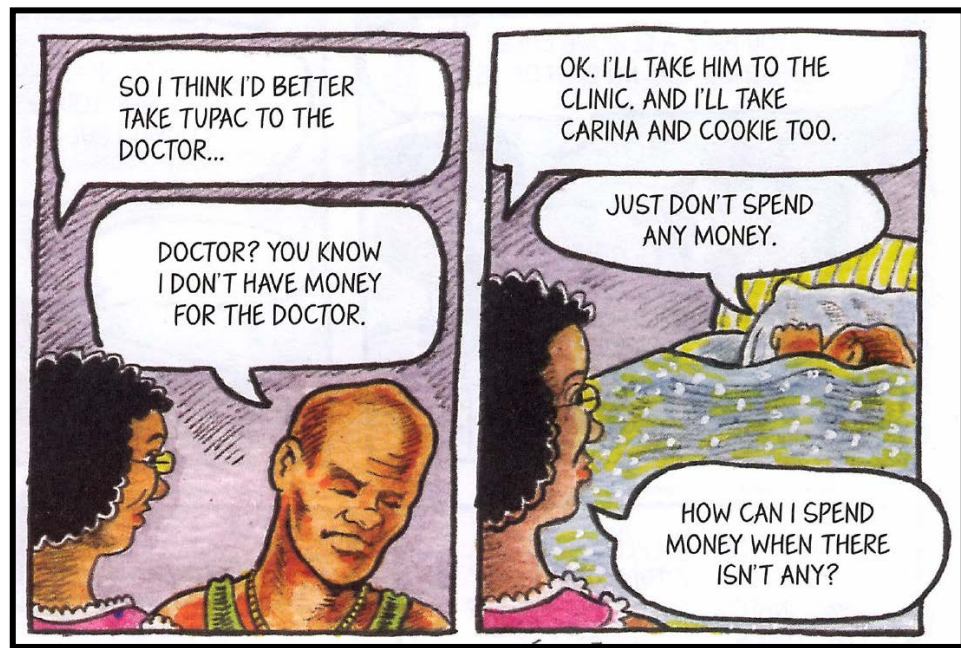


Upon finding out that Tupac has been coughing, Vanessa (Tupac and Carina's Mother), expresses her worry to Vernon (their father), and suggests that it might be TB. At first, Vernon reacts strongly and dismissively – hinting at the silence and stigma surrounding the disease (Abney 2011) – but after being reminded that many they know have had TB, subsequently he concedes that it might be a possibility:



Vanessa says that it would be best to take Tupac to the doctor. However, Vernon, who has recently been laid off from his job at a fruit processing factory, says that they have no money for the doctor – or for anything else for that matter. Therefore, Vanessa suggests that they take him to a government clinic instead:

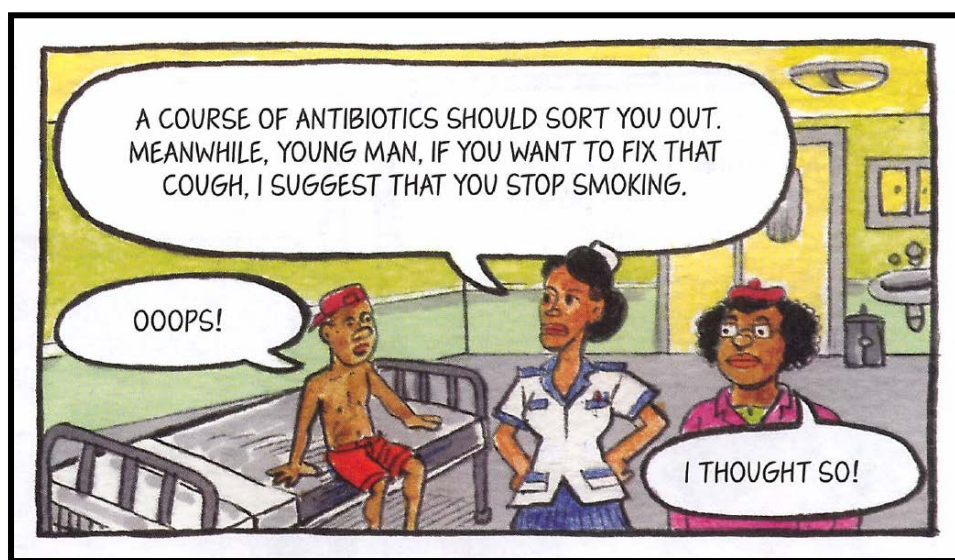




Carina, Cookie, Tupac and Vanessa take the long walk to the clinic and, after waiting in the queue, Tupac is called in by a uniformed nurse. As Tupac is being examined, he is uncooperative with the nurse and is scolded as a result:



It transpires that Tupac does not have TB, but rather a serious chest infection. However, the government nurse tells him that attending the clinic was the right thing to do, given the prevalence of TB in the region. Moreover, realising that Tupac is a smoker, the nurse strongly suggests that he quits the habit:



As this is happening in the consultation room, Carina, back in the waiting room with her baby, is approached by a warm, smiling lady who introduces herself as Mandisa, an employee of SATVI:



Mandisa explains to Carina that, although the Bacillus Calmette-Guérin (BCG) vaccine offers a degree of protection against TB, especially extra-pulmonary TB disease, SATVI



are working towards a new vaccine which offers greater protection against pulmonary TB as well as drug-resistant forms of the disease (e.g. multi drug- resistant [MDR] and extensively-drug-resistant [XDR] TB):



Mandisa then says to Carina that developing such a new vaccine involves many years of clinical testing, and that SATVI are currently starting a large vaccine trial involving thousands of infants. Careful to emphasise that Cookie will not benefit directly from the new vaccine, Mandisa says that Carina and her baby can help SATVI develop a new vaccine that future generations will benefit from by choosing to take part. Wanting to contribute towards this 'greater good', Carina enthusiastically agrees:





A few months later, the Kleynhans family and friends are celebrating Cookie's first birthday. There, one friend voices his suspicions about SATVI's intentions. SATVI, he observes, has been active in the community for years, but so far, they have seen no new vaccine or tangible benefit. He suggests that SATVI might be giving people TB through the new vaccine. Moreover, he questions what SATVI are doing with Cookie's blood. But Carina corrects the man's 'misconceptions':



The conversation goes backwards and forwards, but eventually, and with the help of a member of SATVI's 'community advisory board' (standing to the right of Vernon above), the man's suspicions are put to rest. SATVI, the man comes to realise, is working in the community's best interests and participants have numerous rights in the research. The story concludes with an optimistic look towards the future:



The comic *Carina's Choice* is a useful device with which to begin this thesis because it offers a window into the socioeconomic and epidemiological context of the Breede Valley and also how SATVI conceives of its relationship with the region's residents. The comic highlights the severity of the TB epidemic in South Africa and its close associations with poverty and unemployment (Farmer 2000; Benatar & Upshur 2010). It points out that most residents are reliant upon the government healthcare system, and hints at the strained relationship between the clinics and the people they serve, as depicted by the scene in which Tupac is scolded by the clinic nurse (Jewkes et al. 1998; Walker & Gilson 2004). It also introduces the Western Cape's majority 'coloured' population<sup>1</sup> and, moreover, some of the social challenges that are associated with poverty and which hardened into racial stereotypes in colonial and apartheid imaginings (Jensen 2008, p. 25; F. Ross 2015). This includes absent fathers (Cookie's), young men tempted by gang life (Tupac) and women attempting to be 'true homemakers' with little money or support (Vanessa and Carina).

In terms of how the comic positions SATVI's relationship with its study population, SATVI is unfamiliar to Carina prior to meeting Mandisa, who introduces the institute as standing outside of the local context of health seeking and delivery: representing not intervening upon the region's TB epidemic. Accordingly, the encounter is oriented towards the 'greater good' of a new vaccine, with the comic careful to distance the trials from associations with healthcare or material gain. Moreover, any suspicions about the trials or SATVI's intentions are construed as 'misconceptions', and indeed one of the comic's primary aims as an educational tool was to align local understandings with the imperatives and epistemology of clinical science. However, based upon my fieldwork

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<sup>1</sup> This is one of the racial groups classified by the colonial and apartheid regimes, and will be described further on in this chapter.

at SATVI's trials since between August 2014 and 2015, I would suggest that *Carina's Choice* says more about the language of 'global' science and ethics than it does about how people actually view SATVI and its work. After over fifteen years of being one of the most active non-state presences in the Breede Valley, SATVI has come to hold far greater significance in people's lives than if it were simply a neutral, distanced observer.

This thesis is about the insertion of some of the largest contemporary TB vaccine trials into an impoverished post-apartheid setting which was also experiencing one of the most severe and divisive TB epidemics in the world. I show that despite an image of distance and objectivity characterising formal accounts of SATVI's work (e.g. *Carina's Choice*), the institute has become intricately entwined in the Breede Valley's socioeconomic and healthcare landscape through enduring patterns of enrolment, follow up and referral through to the government clinics.<sup>2</sup> Yet, the significance of SATVI in people's lives is not only that the institute has introduced superior medical resources and expertise into the frame. In fact, my account diverges from others which depict the significance of medical research in the lives of African citizens primarily as a means of accessing scarce resources in the recesses of withdrawing states and ailing health systems (e.g. Geissler et al. 2008; Rottenburg 2009; Kamuya et al. 2014; Nguyen 2015). What emerged during my time with SATVI's participants and staff was not that the trials had steamrolled over social life, purifying new forms of experimental subjectivity, but rather that they had become entangled in people's efforts to craft lives that they considered to be valuable, moral and respectable on the peripheries of social and economic life (F. Ross 2010, 2015).

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<sup>2</sup> As I will explain later, SATVI does not provide treatment for any conditions diagnosed during vaccine trials but rather refers them to their normal healthcare provider, usually a government clinic.

The notion of ‘respectability’ has a long history in South Africa and carries particular weight in the Western Cape (F. Ross 2010). While it has its roots in dominant ideologies of proper personhood, ethnographies in Cape Town have shown that it has been used as a means of struggling back against the poverty, discrimination and stereotyping that have endured into post-apartheid South Africa (Salo 2003; Jensen 2008; F. Ross 2010, 2015). Building upon these studies, I position SATVI alongside other institutions, spaces and strategies in which people struggle back against the inscriptions of the state, with a particular focus on the landscape of health seeking and delivery. A key point of context for explaining how SATVI’s research features in people’s day-to-day lives is the highly-moralised nature of TB in both biomedical and popular discourse and the way that it partially deflects attention away from structural factors and on to individual behaviour and lifestyles. TB has, as I will show, become intimately connected to some of the practices associated with poverty that many residents resented most, including drugs, alcoholism, poor hygiene and gangsterism. One effect is a vicious cycle of responsibility and blame in both healthcare facilities and in low-income areas in which the disease finds greatest traction.

Against this backdrop, SATVI’s trials generated novel relationships and possibilities gravitating around the pursuit of the ‘greater good’ of a new TB vaccine and bioethical ideal of the autonomous ‘human subject’. Within these research relationships, participants not only felt valued, respected and as though they care about personal and community health, in contrast to their interactions with the state. Moreover, I found that during the day-to-day routines of the trials, both participants and staff were bringing their own beliefs, values and ideas about moral, respectable living to bear on their interpretations of the science and the ways in which it could be used it to pursue their hopes for better. I remain careful not to lose sight of the tensions, contradictions and often

futility of people's world-building efforts in a context where life is often cruel and unpredictable (F. Ross 2010). This is reflected in the way the chapters oscillate between people's self-perceptions and moral aspirations, on the one hand, and the multiple conditions, especially where TB is concerned, under which negative stereotypes resurface and are activated (in particular, the *skollie* [thug] and the 'problem TB patient'). Nonetheless, what emerges from this account is a moral economy<sup>3</sup> that, firstly, challenges the abstract tenets of formal research ethics and specifically the bioethical construction of 'vulnerability'. Secondly, this moral economy unsettles a trend in social research to emphasise the material dimensions of trial participation at the expense of a broader spectrum of imperatives and subject positions from which people approach and interpret medical science.

## Globalised Clinical Trials

Since the turn of the 21<sup>st</sup> century, there has been a greater acknowledgement of the widening health disparities between the global north and south and the failure of markets to address the needs of the world's poorest (Farmer 1996; Lock & Nguyen 2010). In the wake of the civil society movement spearheaded by Médecins sans Frontières and Oxfam, a number of major pharmaceutical companies, governments and newly founded not-for-profit organisations (e.g. the Gates and Rockefeller Foundations) began to direct substantial research and development (R&D) activity towards previously 'neglected' diseases, particularly HIV/AIDS, TB and malaria (Pecoul et al. 1999; Trouiller et al. 2002; Hanson et al. 2012).<sup>4</sup> The term 'global health' has come to refer to both the

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<sup>3</sup> I use Lorraine Daston's (1995, p. 4-5) definition of a moral economy: "a web of affect-saturated values that stand and function in a well-defined relationship to one another...but not always predictable in their details" (see also Daston & Galison 2007).

<sup>4</sup> Other diseases such as lymphatic filariasis and schistosomiasis remain neglected to the present day (Allen & Parker 2012).

increasingly transnational nature of health threats and the vast assemblages of government and non-governmental actors working to overcome them (Lock & Nguyen 2010; Hanson et al. 2012). In the era of global health, research and development activity is increasingly conducted under the guise of product development partnerships. Supposedly combining the best of both worlds – public health interest and funding with private-sector efficiency – product development partnerships are now a prominent source of new drugs and vaccines.

The research programme with which this thesis is interested is the pursuit of new and improved vaccines to combat TB. TB was labelled a ‘global emergency’ by the World Health Organisation (WHO) in 1993 and remains one of the most prevalent and deadly infectious diseases in the world. In 2015 alone, there were 10.4 million new cases of TB, 1.4 million deaths from TB among HIV-negative individuals and 400,000 additional deaths among HIV-positive individuals (WHO 2016). Notably, 95% of positive TB diagnoses and 98% of TB-related deaths happen in developing countries, where the conditions under which the disease thrives – inadequate food security, unhygienic and crowded living conditions, and poor access to healthcare – are abundant (Benatar & Upshur 2010). The *Bacillus Calmette-Guérin* (BCG) vaccine has served as the only vaccine used on a global scale since its introduction in the former half of the 20<sup>th</sup> century. It has had a positive impact, and has been shown to reduce the risk of pulmonary TB in infants by upwards of 50% on average (although its efficacy is subject to regional variation (Colditz et al. 1994). However, it is widely thought to be insufficient as a self-standing TB preventative, especially given the continuing proliferation of multi- and extensively drug-resistant strains of the disease (MDR and XDR). Thus, the goal at present is the production of a booster vaccine which will increase the overall efficacy of



the BCG vaccine or, alternatively, to find a self-standing vaccine that is sufficient to replace the BCG given at birth.

Like all biomedical drugs and vaccines, those products that are destined for the humanitarian market must undergo extensive clinical trialling in order to attain approval from major regulatory bodies such as the US Food and Drug Administration (FDA). Consequentially, in a transition paralleling the ‘offshoring’ of clinical trials in the private sector (see Petryna et al. 2006; Petryna 2009; Sunder Rajan 2006), these products are increasingly tested in middle- and low-income countries in collaboration with host-country NGOs and research institutes (Marks 1997; Hanson et al. 2012). Established in 2001, SATVI is one of the largest research institutes running TB vaccine trials in Africa, in collaboration with Aeras Global Vaccine Foundation (a Gates Foundation-funded PDP), Oxford University and a variety of other northern institutions and companies (see Chapter 2).

The trialling of drugs and vaccines on human subjects raises important questions of ethics. Since the atrocities committed under the Third Reich, various ethical guidelines have emerged and been gradually fine-tuned to ensure the protection of human subjects. These include the Nuremburg Code (1947), Declaration of Helsinki (1964), Belmont Report (1978) and, perhaps most significantly, the International Conference on Harmonisation and Good Clinical Practice (ICH GCP). Spearheaded by the US Food and Drug Administration (FDA), ICH GCP was introduced in 1995-1996 in order to synthesise existing norms, both scientific and ethical, into one “international ethical and scientific quality control standard for assuring the protection of subjects and quality of data” (Petryna 2009, p. 24). Good Clinical Practice (GCP) has a number of versions, having been adapted to be more relevant in the settings in which it is implemented (e.g. South Africa has its own version which was introduced in 2000 and updated in 2006).



Separate from the previous codes that it incorporates, today GCP is *the* industry standard for the regulation of human subject research and has largely succeeded in enabling a globalised network of standardised clinical trials.

GCP prescribes an array of measures, including high standards of care (and the minimisation of placebo-controlled trials), ensuring that the benefits outweigh the risks, and stringent monitoring and oversight. But with numerous examples etched into the popular memory of people being coerced into medical research, the bioethical principle that lies at the heart of research ethics is that of autonomy. The human subject, as Geissler (Geissler 2013, p. 18) explains, “is not a subject of control, compassion, or responsibility, not defined by a relation of inequality, but a free rational agent, whose participation in medical research is not derived from a logic of responsibility or care but of choice”. The practice that is primarily responsible for upholding this freedom is informed consent, the “*sine qua non* of human experimental research” (Sariola & Simpson 2011, p. 515). Informed consent involves the clear communication of information about research, which demonstrates that people are in a position to make rational, informed decisions whether to take part (see Molyneux & Geissler 2008; Sariola & Simpson 2011; Hoeyer & Hogle 2014; De Vries & Henley 2015). Given the emphasis on autonomy, the ideal scenario (that informed consent is supposed to bring about) is one in which people take part for the ‘greater good’ that the research will bring about – be it a drug, vaccine or new knowledge – and not for the immediate benefits of participation. Situations to be avoided at all costs are expressed by telling phrases such as ‘undue inducement’ (where the material benefits are enough to sway people into participation against their better judgement) and ‘therapeutic misconception’ (where people believe the research is for their healthcare when it is not and could, to the contrary, cause them harm).

Conducting ‘ethical’ research is therefore a huge challenge in settings where people are incredibly poor, with low rates of scientific and health literacy, and where access to healthcare is severely compromised. In the language of bioethics, people living in poverty are considered, to varying degrees, to be ‘vulnerable’ – a key trope in bioethical discourse that features in research guidelines and has received critical attention in attendant scholarship (e.g. Kipnis 2001; Levine et al. 2004; Horn 2007; Tameris 2010; Ten Have 2016).<sup>5</sup> Geissler (2013, p. 18) argues that while poverty is taken seriously in bioethical discourse, the priority afforded to autonomy (over distributive justice) means that material inequality should not be redressed by researchers but rather mitigated against. The possibility of ‘undue inducements’ and ‘misconceptions’ can in theory be neutralised through keeping material benefits in check and communicating clearly to participants about what the research is and what it is not. Consequently, with the exception of a minority of bioethicists who are interested in issues of distributive justice in medical research (Benatar 2002; London 2005; Macklin 2004; Pratt & Loff 2011; Pratt & Loff 2013), most bioethical debate has centred on how best to preserve the autonomy of vulnerable individuals by devising ever ‘stronger’ consent procedures (Hoeyer & Hogle 2014).

## Neoliberalism and Global Health

Not satisfied with the assumptions upon which bioethical guidelines rest, an expanding body of anthropological literature has sought to put clinical trials back in the political and economic contexts from which they have been divorced. Analysing the ways that clinical

---

<sup>5</sup> Kipnis (2001) offers a taxonomy of vulnerability. Kinds of vulnerability include: poverty and educational deprivation; cognitive (ability to understand and make choices), medical (having a disease for which no treatment exists), juridical (being under the legal authority of someone), deferential (accustomed to having decisions made for them) and infrastructural (whether research setting has the necessary capacity to carry out the research).

trials are ‘offshoring’ in the private sector, Petryna (2009) observes certain developing countries (e.g. Brazil and Poland) are being targeted for trials because of their relatively strong medical and research capacity, availability of poor trial participants with lack of access to healthcare and a legal system that is conducive to the conduct of clinical trials (see also Sunder Rajan 2006; Cooper 2008). A key part of this increasingly global trial assemblage is GCP. Because of its narrow focus on the researcher-subject relationship (as opposed to the broader socioeconomic contexts of this relationship), GCP enables the conduct of trials that might not be permissible in the developed world (see also Rennie 2009; Douglas-Jones 2012; Simpson et al. 2015). Petryna (2009) uses the term ‘experimentality’, a play on Foucault’s term ‘governmentality’, to capture the overarching logic of this highly profitable industry intent on enrolling the world’s poorest people into clinical trials.

On first glance, it appears that the humanitarian market, which is not profit-driven and explicitly intended to reduce global health inequities, is separate from such processes. However, recent scholarship has situated clinical trials within a broader shift in power in Africa from national governments to an assortment of international non-state actors under the umbrella of ‘global health’. The backdrop for this argument is the neoliberal reforms imposed on many African nations during the 1980s that led to the withdrawal of the state from key functions, including healthcare. Into this space have moved a variety of actors – UN organisations, charities, NGOs, northern universities and research institutes – which often completely bypass state institutions. In contrast to imaginings of comprehensive, community-based care following independence in many African nations, these humanitarian interventions extend only to the minimal form of care required for survival (Prince 2014). Moreover, their territories are arranged in more of an “archipelago” pattern than providing even coverage, concentrated especially in regions with high burdens of

disease (Rottenburg 2009; Geissler 2014). Nonetheless, they have largely taken over the state's responsibility for the provision of healthcare in a "new form of fragmented sovereignty" (Rottenburg 2009, p. 426).

In the new era of global health, medical experiments and humanitarian interventions constitute a powerful form of social organisation in the everyday lives of Africans. Building upon previous work on "biosociality" (Rabinow 1996; see also Petryna 2005), Nguyen has coined the term "therapeutic citizenship" based on his work in West Africa to capture the way in which claims to resources essential for survival are contingent upon biological status, especially HIV and AIDS (Nguyen 2005, 2010, 2011). He argues that clinical trials "catalysed the formation of community-based organisations and self-help groups focused on gaining access to resources" that "became veritable therapeutic communities" (Nguyen 2011, p. 429). In self-help groups, people had to employ testimonials based upon Western confessional technologies, with members effectively competing with one another to demonstrate who made the best advocates in order to secure treatment (Nguyen 2010). Similar transformations of subjectivity have been observed by Robins (2006) in South Africa, who shows how, upon becoming members of the Treatment Action Campaign (TAC), people became "responsibilized citizens", living "positively" in accordance with the demands of antiretroviral therapy. In a recent paper, Nguyen (2015) takes this argument yet further. Analysing Treatment as Prevention (TasP) trials, he goes so far as to suggest that these huge clinical trials are now so ubiquitous that they "herald the birth of experimental societies" (2015, p. 47), that is, entire populations that are governed from afar according to the inexorable logic of experimentality.

## **The Interface Between ‘Global’ and ‘Local’**

While the above scholars have drawn attention to the political economy of clinical trials and how they shape experimental subjectivities and social life, what they tend to be less attentive to is that ‘global’ scientific and ethical norms must contend with existing constellations of culture, history and politics (Sariola & Simpson 2011). Another line of anthropological enquiry has focused upon the dynamics of particular trial sites to highlight the creativity that is required for making ‘global’ research structures work in settings that are different to the global north, both culturally and economically. Issues explored include: establishing ethical review committees (McIntosh et al. 2008; Douglas-Jones 2012); eliciting informed consent and maintaining ‘ethical’ relationships during clinical trials (e.g. Gikonyo et al. 2008; Geissler et al. 2008; Leach & Fairhead 2011; Kelly 2011; Sariola & Simpson 2011; Reynolds et al. 2013; Kingori 2013); ‘reimbursing’ participants for study visits (Geissler 2011); running community engagement projects (Marsh et al. 2008; Marsh et al. 2011); and working in contexts of medical paternalism (Simpson & Sariola 2012).

A number of these studies were conducted at large, northern-funded medical research institutes in Africa that make up the “archipelago” (Geissler 2014) of global health (e.g. the British MRC in The Gambia and KEMRI in Kenya). With SATVI sitting alongside these institutes in terms of size, scope and influence in the communities with which they work, it is useful to say something more about the social dynamics of African “trial communities” (Geissler et al. 2008). Standing out from the poverty and under-resourced healthcare facilities around them, they have become a familiar part of the local context of health seeking and delivery, providing basic healthcare for participants – sometimes whole communities – that far surpasses that which their governments are able to provide (Geissler et al. 2008; Leach & Fairhead 2011; Kelly 2011; Kamuya et al. 2014).

Against this backdrop, for those on whom research is conducted, research is often not about the objective, disinterested collection of data for the ‘greater good’ but rather a means to access healthcare or material resources. As Geissler and colleagues observed during a British MRC vaccine trial in The Gambia, the moral economy of truth and objectivity prized by science had to coexist with another on the ground, involving “material contact and substantial transactions, notably of blood and medicine” (Geissler et al. 2008, p. 696; see also Lock & Nguyen 2010, p. 199).

Because material transactions are not recognised by formal research ethics, considerable ethnographic attention has been paid to the work of frontline research staff, and especially fieldworkers. Speaking participants’ languages and knowing local values and customs, these actors are hired locally to perform ‘simple’ tasks, including obtaining informed consent and also some aspects of data collection (Molyneux et al. 2013). Yet, with allegiances to both research institutes and participants, it has been shown that their work is far from simple and that they play a creative, ethically-charged role balancing the objective requirements of protocols with the needs and expectations of participants and their communities (Geissler et al. 2008; Molyneux et al. 2010; Molyneux et al. 2013; Reynolds et al. 2013; Kingori 2013; Kamuya et al. 2014). ‘Relational ethics’ – the ethics of face-to-face encounters – has come to describe the work that these frontline researchers engage in: a necessary if obscured corollary to the distanced, abstract tenets of formal research ethics (Molyneux & Geissler 2008; Geissler et al. 2008; Molyneux et al. 2010; Posel & Ross 2015). Recently, Geissler (2013) has broadened this picture to suggest that an activity in which all research staff, from the lowest to the highest, implicitly engage is that of “unknowing” material difference. During research encounters, there are certain contexts in which difference can be “known”, for instance informal discussions in side corridors and after study visits. But in the formal protocols and practices of research, the

material inequalities between researchers and impoverished participants, between research institutes and government healthcare facilities, even between northern scientists and their African counterparts – these must all be conveniently “unknown” – in order to maintain the values of autonomy, distance and equal collaboration upon which transnational research is premised (Geissler 2013, p. 17).

The ‘trial communities’ literature importantly highlights the creativity and relational work that is needed on the ground in order to make ‘global’ science and ethics operable in contexts of material inequality. However, its critique, while broadening the purview of research ethics in one respect (drawing attention to the wider political economic context of trials and the hidden work that is needed in such settings), is arguably also restricted in another. In seeking to unsettle the bioethical ideals of ‘autonomy’ and ‘material independence’, the significance of trials in people’s lives is largely reduced to providing access to scarce medicines and resources against the backdrop of withdrawing state structures. This is similarly true of Nguyen’s (2005, 2011) notion of “therapeutic citizenship”, which refers to how people’s claims to resources for survival are being redirected through trials and humanitarian interventions on the basis of biological states. My worry is that the emphasis on the material dimensions of participation, described using state-citizen metaphors, is at the expense of a broader appreciation of the spectrum of roles, imperatives and subject positions from which people approach and interpret clinical trials.

In a recent study, Brives (2013) expresses a similar concern. Her position is that while the category of the human subject has received considerable social scientific attention, the significance of trials for participants has tended to be reduced to their clinical benefits, with the effect that their lived realities tend to be “cut loose from the very practices that constitute the beating heart of the trial” (2013, p. 398). Analysing a

clinical trial in Burkino Faso involving HIV-positive mothers, Brives shows that the trial operated according to a very different logic to the rushed and under-resourced government healthcare context outside the trial environment. Specifically, much effort was made to engage the mothers one-on-one so that they adhered to the meticulous standards of the trial protocol (2013, p. 410). An unintended effect was that, in participating in their own objectification, this scientific way of being had significant ramifications for the mothers beyond the trial. For instance, for the women, what it meant to be a “good mother” emerged in conversation with supposedly mundane bio-scientific practices. Brives argues that:

The mother-child pairs exist as research objects, yet not exclusively: they also exist as women, daughters/sons, employees, loved ones and so on. The trial might determine, in part, what choices the women make and impose numerous exigencies; yet, the women never emerge as passive objects, subjected to the authority of research. (2013, p. 412)

In drawing attention to the ways in which the authority of research is challenged in everyday research practice, Brives’ observations suggest a line of critique that moves in another direction to much current anthropological scholarship. We arguably already have an established critique of the bioethical ideals of ‘autonomy’ and ‘equal collaboration’. Yet what has received considerably less critical attention is the (closely associated) bioethical construct of ‘vulnerability’.

The notion of vulnerability, as noted above, references ‘compromised autonomy’ in the context of bioethics and features prominently in research guidelines to justify additional protections to certain categories of participant (see Kipnis 2001). A growing body of bioethical and social science literature has problematised the category and its ever-expanding applications, especially in developing world settings where poverty and



‘vulnerability’ have become closely entwined (Chambers 1989; Levine et al. 2004; Furedi 2008; Reynolds 2014; K. Brown 2015). Levine et al. (2004) argue that the bioethical use of vulnerability is both “too broad” and “too narrow”. It is too broad in the way that it is placed a priori over whole populations on the basis of socioeconomic status. This not only makes the term too nebulous to be meaningful but also reinforces negative stereotypes of the poor (ibid 2004, 47). Chambers argues that the category is generally imposed by policy makers under the assumption that “they know what poor people want and need” (usually income and consumption), positions them as defenceless, fragile and deficient, and reinforces an image of the “amorphous and undifferentiated mass of the poor” (Chambers 1989, p. 35). ‘Vulnerability’ is also too narrow in the way that it is focused solely on characteristics that bear on people’s capacity to freely choose. As Levine et al. (2004, p. 46) argue, this focus deflects attention away from other features of the institutional, social and economic context that can expose participants to harm. Moreover, it greatly limits our insights into what clinical trials might mean to those labelled ‘vulnerable’.

By way of a response to the bioethical construction of vulnerability, this thesis strives to view ‘vulnerability’ not as an a priori and imposed category referencing ‘compromised autonomy’, but rather as emergent in practices. I will show how vulnerability was interpreted and acted upon, both by clinical trial participants and research staff, in ways that might not be visible from the abstract perspective of bioethics. Taking ‘lived experiences’ of vulnerability as an empirical focus reveals an array of ways in which people felt vulnerable in their social and material environment; but it importantly allows us to see them not as not to be simply ‘fragile’ or ‘defenceless’ but rather innovative, dynamic and resilient in the ways in which they navigate complex sociomedical spaces (Beck & Nesmith 2001; F. Ross 2010; Reynolds 2014; Reynolds

2015; K. Brown 2015). Indeed, one of the primary reasons that SATVI's trial environment was valued, I will show, is that people felt that they were treated as autonomous, rational and responsible in a way that they were not in other health settings. It is my hope that this approach will enable us to move beyond the narrow bioethical framing of the human subject that is captured between the poles of 'vulnerability' and 'autonomy' and instead to gain a more holistic understanding of how medical research features in people's lives in South Africa.

### **Respectability in Post-Apartheid South Africa**

Despite the end of apartheid, South Africa remains highly segregated, still barely making inroads into centuries of racialised exclusionary policies that were initiated during the colonial period and further entrenched under apartheid. The Western Cape is unique case in relation to the rest of the South Africa. As within the country more generally, a sharp, racially-based distinction was drawn between 'White' and 'Black'. However, this distinction was complicated in the case of those labelled 'Coloured'<sup>6</sup>, who, on the basis of lighter skin than black people, were viewed with ambivalence: neither the antithesis of white civilization nor included within it. This ambivalence was reflected during apartheid when coloured people were situated, both hierarchically and spatially, in a sort of "buffer zone" between white and black people (Jensen 2008, p. 2). Cape Town and surrounds were declared a Coloured Labour Preference area in 1954, and black people were restricted from living permanently in the urban centres except under the most extreme of circumstances and relegated to the ethnic 'homelands' or otherwise forced into illegal

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<sup>6</sup> The denotations of racial groups in South Africa has shifted over time and been hotly contested. In this thesis, racial categories appear as they do in the South African census (2011). That is: 'White', 'Coloured', 'Black African' and 'Indian'. I will not usually place inverted commas around them, although I am aware of the violent histories of these terms and the complexity of South African identity politics. Unless contextually appropriate, I will use first language rather than racial classification to describe participants.

squatter camps (F. Ross 2010, p. 2). In practice, however, living conditions were little better for coloured people during apartheid, and many of these people were eventually forced into illegal squatter camps alongside black people.

The notion of respectability has a long history in the Western Cape (R. Ross 1999; Salo 2003; Jensen 2008; F. Ross 2010). It is captured within the Afrikaans term *ordentlikheid*, which connotes “decency, respectability, reasonability, and proper conformity to the social norms of the elite” (2015, p. S98). Under colonial rule, ‘respectability’ was an organising principle around which unequal social relations were built, and it came to be defined primarily in Christian terms, both legitimising racial divisions and providing a frame for “saving” Africans (R. Ross 1999; Hull 2009; F. Ross 2015). While it is rooted in dominant notions of personhood, especially what it means to be a ‘proper’ woman, a number of ethnographic studies have shown that *ordentlikheid* has become an emic term in Afrikaans-majority townships in Cape Town, used to lend meaning to life in adverse circumstances and in the process taken on meanings not necessarily envisaged by the state (Salo 2003; Jensen 2008; F. Ross 2010). Fiona Ross (2010) conducted research in an informal settlement called The Park, the residents of which were awarded formal housing rights after apartheid. She shows that their hopes “crystallised around the notion of *ordentlikheid*” (ibid, p. 3) and examines the possibilities, tensions and contradictions surrounding their hopes to become recognised as decent and respectable people. Steffen Jensen (2008), in a township called Heideveld where poverty was less grinding, explores a broad array of ways in which men and women sought to attain dignity and respectability. This includes religion, community politics, sports, religion and even gang life.

Jensen (2008) importantly argues that claims to dignity and respectability in Heideveld were constructed in response to the stereotype of the *skollie*. The term literally

translates as ‘scavenger’. But in Cape Town it came to mean ‘thug’ or ‘hooligan’ and refers to someone who is poor, male and coloured, refuses to work, is a criminal, drinks and terrorises working people (ibid, p. 2). The *skollie*, Jensen argues, is closely entwined in the construction and governance of the coloured population. While coloured people were viewed as being some way closer to white civilization than black people, various commissions into coloured life (e.g. the Wilcocks Commission [1937]) framed them in a very negative light. With almost no regard for the poverty in which they were forced to live, they were portrayed as “lacking in commitment and moral fibre, and a general image of the coloured problem family in need of state attention was evoked” (ibid, p. 25). The most problematic member of this stereotypical family was the father, who undermined the mother’s “uphill battle to be a true homemaker” through being “absent, shirking his responsibilities and indulging in alcohol” (ibid, p. 25). Through his absence, the children were likely to go astray and become “antisocial, that is, *skollies*” (ibid, p. 25). Jensen argues that the *skollie* has been gradually objectified, acted upon and made real in the Foucauldian sense by successive governments and bureaucracies, and has endured through democratic transition into post-apartheid South Africa. Jensen (ibid, pp. 4-5) shows that today the *skollie* occupies an ambiguous place for township residents. On the one hand, he undermines positive coloured identities because people are associated with him through race; but on the other, people position their own morality and respectability by projecting the *skollie* elsewhere and on to others. Following Gramsci’s notion of dual consciousness (cited in Gutmann 1996), he explains that:

Colouredness is split between individuals’ everyday sense of being themselves as persons who live normal and moral lives on the one hand, and on the other the colouredness, sustained by the full gamut of stereotypical framing and definition. These two forms of consciousness exist

simultaneously but not on an equal level. The form of consciousness based in governmental framing and definition might be repudiated, but it will never be entirely expunged. It can always return to undermine the sense of self. (2008, p. 8)

The context in which I was working, like Ross (2010), is more heterogeneous in terms of racial and linguistic makeup than Heideveld (Chapter 2, p. 48), and therefore it would be misleading to overemphasise the coloured population and its challenges over those of others. Nonetheless, Jenson's use of 'dual consciousness' resonates strongly with my own experiences with SATVI's participants. Moreover, taken together, these ethnographic studies demonstrate the profound effects that the categorisations and interventions of the colonial and apartheid regimes have had on the lives of South Africans and that continue to threaten the conditions for being able to lead ordinary, respectable lives. Yet with considerable ingenuity this is precisely what many people have managed, however partially and temporarily. These ethnographies do much to draw attention to what it means to inhabit conditions that produce extreme vulnerability and the ways in which people not only find the means to survive but to recover from their circumstances the elementary particles of social life.

### **TB, Morality and the Human Subject**

One might well ask what people's attempts to craft moral, respectable lives has to do with the TB epidemic and SATVI's research to produce a new TB vaccine. But one thing that will become clear is that TB is far from simply a biological organism, one that can be acted upon and researched as a brute biomedical fact. It is, in many ways, the archetypal disease of poverty (Farmer 2000), finding traction in exactly those spaces where life is at its most abject: cramped and overpopulated houses, lack of sanitation, malnutrition and

other infectious diseases (e.g. HIV). Moreover, in tandem with HIV and AIDS, with which TB is closely associated<sup>7</sup>, the disease is highly moralised in biomedical discourse through the neoliberal language of patient ‘responsibility’ (Compion 2008). The treatment of TB is framed as a matter of individual ‘adherence’ and, consequently, places blame for the continued proliferation of the disease upon sick individuals and their communities (Farmer 2000; Compion 2008; Harper 2006; Harper 2010). As Abney (2011) shows in a study of TB-related stigma in Khayelitsha, Cape Town, TB discourse is further moralised in local symbolic repertoires, closely associated with notions of ‘dirt’ – not only dirty places but dirty *people* and dirty *practices*. It is, I will suggest, closely tied to some of the practices that were viewed by residents as the biggest threats to a moral community, including alcoholism, drugs, poor hygiene and gangsterism.

While in Jensen’s (2008) work the stereotypical figure of the *skollie* is the protagonist, in this thesis I introduce another stereotypical figure, one partially overlapping with that of the *skollie* (for the *skollie* often has TB – alluded to by the character Tupac in the comic *Carina’s Choice*) but distinct from him. This is the ‘problem TB patient’. Similar to the *skollie*, he is a product of governmental categorisation against which morality and respectability is set. The problem TB patient is not necessarily male, nor coloured, but almost certainly not white. He is likely to be seen drinking, smoking or doing drugs and practicing poor hygiene (e.g. spitting in the street). He might not yet have been diagnosed, but is visibly sick and refusing to go to the clinic for treatment, consequently spreading TB to the innocent, especially children and the elderly. Worse, he might have begun treatment but prematurely stopped – ‘defaulted’, in biomedical

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<sup>7</sup> HIV is largely responsible for the scale of the TB epidemic in South Africa because TB is one of the opportunistic infections to which HIV-positive people are highly susceptible. In the early 2000s, the diagnosis and treatment of TB and HIV began to be integrated in government healthcare facilities (Compion 2008).

discourse – running the risk of developing and passing on drug-resistant strains of the disease. Unlike the *skollie*, the ‘problem TB patient’ is a stereotype produced through the health sector, and has not been a matter for the police since the end of apartheid when patients were afforded the right to refuse treatment (Patient Rights Charter 1996). Falling squarely under the jurisdiction of under-resourced government clinics, he is framed not as a criminal but rather as a threat to public health through his purported ‘irresponsibility’.

TB is by no means the only challenge that the government clinics struggle with. For instance, HIV and AIDS, chronic diseases, other STDs and antenatal care all place a large strain on the clinics. Nonetheless, I will argue that given the magnitude of the TB epidemic and surging rates of ‘defaulting’, it is a key contributor to a common perception among government clinic staff that the communities they serve seem unwilling or unable to ‘take responsibility’ for their health. As alluded to by the interaction between Tupac and the nurse in *Carina’s Choice*, practices of scolding are commonplace occurrences in the government clinics. Although I am careful to articulate nurses’ side to the story (Chapter 4; see also Joyner et al. 2014), many residents felt that when entering a clinic they were immediately placed in the role of the irresponsible patient and that they were treated without respect and as on the bottom of a hierarchy similar to that during apartheid healthcare (Chapter 7). TB discourse, I will argue, is especially insidious in the way that it deflects attention away from structural determinants of disease and reproduces a cycle of blame both in healthcare facilities and in the communities in which the disease finds traction.

It is against this backdrop that many people were approached by one of SATVI’s fieldworkers and were asked whether they would like to take part in a TB vaccine trial (Chapter 5). In order to help explain what SATVI’s trials mean in such a context, the following chapters are constructed empirically around a schema that I have adapted from

Sariola and Simpson (2013). At the point at which people were enrolled into trials, they might be considered *abjects*: in my usage, people for whom the conditions for leading normal, healthy and respectable lives have been rendered precarious by centuries of discrimination and exclusion.<sup>8</sup> However, because of the close association between poverty and TB, it is in this state that they become valuable “*objects* of research and experimentation – they are available bodies that provide measurements, samples and pathologies to be observed” (ibid, p. 42). In the process, they become “reconfigured as universal human *subjects*” (ibid, p. 42), that is, autonomous, rights-bearing individuals who have more power and inclusion in the decision-making process than in ‘normal’ healthcare relationships (for example between Tupac and the clinic nurse in *Carina’s Choice*) (see Chapter 3).

Beginning with a history of SATVI, I will demonstrate that constructing a research environment gravitating around the remote authority of GCP and the universal human subject was a challenging undertaking in a deeply rooted culture of medical paternalism (Chapter 3; see also Simpson & Sariola 2012). Nonetheless, I will show that, at the time my fieldwork, most of SATVI’s research staff embraced the ‘flat’ nature of research relationships (Chapter 5) and, in turn, participants appreciated being made to feel valued, included and as though they genuinely care about their own health and that of others. Indeed, I will argue that one of the most important reasons that SATVI has become engrained in the local context of health seeking and delivery is because of how the research relationships starkly contrasted with the authoritarianism of the government clinics (Chapter 7).

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<sup>8</sup> Sariola and Simpson use the notion of abjection with Kristeva's (1982) conception in mind and to characterise self-poisoning patient-participants in Sri Lanka. I use this term tentatively because, like the term ‘vulnerable’, it is not necessarily something that participants would consider themselves to be. However, I believe that it is a useful starting point for highlighting why they tended to view SATVI in a very positive light.



Moreover, within the more dialogical relationship generated by the research environment, the category of the human subject was not ‘universal’ (as it is viewed in bioethics) but rather a surprisingly open-ended signifier. As I will show, both participants and staff were projecting their own beliefs, values, self-perceptions and moral aspirations on to the category of the human subject and what it meant to take part in TB vaccine trials. Indeed, in the same moment that the trial protocols were shaping participants as standardised and commensurable bioscientific *objects* (Lock & Nguyen 2010; Brives 2013), on the ground it was the moral *subject* that was the primary locus of knowledge and intervention. Importantly, the meaning-making that surrounded the human subject also spilled into understandings of the science itself (and how it could be used). One common understanding of SATVI’s trials, I will show, was in terms of donations of ‘clean blood’, which condenses a highly-moralised understanding of trial participation that collapses the distinction between object and subject altogether (Carsten 2013a). The idiom of ‘clean blood’, I will suggest, contrasts starkly with the way in which trial protocols construe participants’ scientific value in terms of a passive disposition to sickness, one in which participants are simply drawn from and representative of a ‘high-burden community’. Rather, it reflects people’s desire and commitment to be set *apart* as moral, responsible and respectable individuals, sometimes leading to radical transformations in outlook and lifestyle that had profound effects on their lives beyond the confines of the trials (Chapter 6).

At the same time that SATVI was seen as a place for the betterment of self and society, however, the figure that such moral personhood was defined against – the ‘problem patient’, the *skollie* or others engaging in ‘dirty practices’ – was never far away. In fact, he was seen both by participants and research staff to be very much attracted to

the trials because of the promise of regular monetary ‘reimbursements’<sup>9</sup> (cf. Geissler 2011). From the perspective of research staff, the presence of people seemingly only there ‘for the money’ was often taken as a unique opportunity to work with and on certain participants to instil in them with their own values. Yet for most research participants, this meant conscious efforts to distance and disassociate themselves from the monetary incentive. For instance, during interviews, it was striking how many people’s narratives of participation began with the phrase, “it’s not about the money, it’s about...”, usually followed by a reference to personal health and/or altruism (Chapter 6). Following Jensen (2008), I contend that one of the contradictions underlying SATVI’s entanglement in people’s attempts to frame themselves as valuable, moral and respectable was that it relied on pointing fingers at other people, reinforcing the very stereotypes and structures of dominance that they sought to escape. The limits and often futility of people’s attempts to dissemble the structural violence that shapes them are discussed most explicitly in Chapter 8. This chapter shows that, despite their self-perceptions as responsible, health-seeking individuals, participants who were diagnosed with TB did not always attend a government clinic for treatment, prompting collaborations between clinic and SATVI staff to ‘track them down’. In fact, insofar as the government clinic staff were concerned, the subsidiary function of SATVI’s trials was to extend their reach into hard-to-reach, gangster-ridden settings and exert control over the elusive bodies therein.

What ultimately emerges from this thesis is a different moral economy surrounding trial participation than, for instance, that of substantive transactions of blood and medicine identified by Geissler and colleagues (2008). The significance of SATVI’s trials in people’s lives, I will show, goes beyond providing access to scarce resources

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<sup>9</sup> These ‘reimbursements’ were R150 per study visit (approx. £9 at the time of writing). These are detailed further in Chapter 3, p. 87 and Chapter 5, p. 145.

against the backdrop of withdrawing state structures. In fact, people often expressed a sharp resistance to material gain, at least where money was concerned, as they struggled back against the state's inscriptions. This moral economy instead incorporates values such as respectability, cleanliness, 'good' lifestyles and responsibility, and is partially defined in opposition to the associations between TB and 'dirt'. Insofar as this thesis offers a critique of bioethics, therefore, it is not a critique of 'autonomy' and the language of 'choice'. For in my experience, these mapped closely onto the way people did or wanted to view themselves. One thing that participants would object to, however, is being placed uncritically into the bioethical category of 'vulnerable'. Participants, as I will show, experienced vulnerability in an array of social spheres, including the grinding effects of chronic poverty, the threat of gang violence or pressure to join gangs, disease and stigma, and the perceived indignities of their interactions with the state. But SATVI was not among them. In fact, the institute was a place in which people felt safe and, moreover, was a platform from which to confront or avoid other kinds of vulnerability. To apply this category a priori not only misses the ingenuity with which people build worlds on the peripheries of social and economic life and, specifically, how they interpret and appropriate medical science. It is potentially even harmful given how hard they worked to escape stereotypes of themselves. To resist one stereotype only to be reframed as 'vulnerable' – which, as Chambers (1989, p. 35) argues, sustains images of the “amorphous and undifferentiated mass of the poor” – seems a gross injustice. This ethnography is about how people attempt to build lives in post-apartheid South Africa and how clinical trials can become a part of their search for a better future – a situated moral project taking place under the radar of the bio-scientific pursuit of the 'greater good' of a new TB vaccine.

## The Chapters

**Chapter 2** provides a description of the field site and study design. This includes information about SATVI's trial site and post-apartheid Worcester, as well as sections on methodology and the ethics of fieldwork.

**Chapter 3** offers a history of SATVI. It shows showing how research capacity was built for some of the world's largest TB vaccine trials against the backdrop of an emerging field of global health science and an enduring history of apartheid governance. Drawing on the memories of SATVI's first team, I elaborate upon the statement made by SATVI's first site manager that "we learned research by actually doing it". This included building the site, establishing trust with government workers, adapting to a researcher-subject (as opposed to healthcare provider-patient) relationship, and learning GCP. While the chapter focuses upon SATVI's first trial, "the BCG study", it ends with an account of developments between that study and the present, especially the landmark infant trial between 2009 and 2012.

**Chapter 4** describes the context of TB control within the scope of SATVI's operations from the perspective of government clinic staff and especially nurses. I show that the nurses were struggling with a dissonance between the post-apartheid imagining that people would 'take responsibility for their own health' and the reality of patients not attending the clinics when sick and 'defaulting' on treatment when they did. The 'gap' between the clinic and home was viewed as one of the main challenges of TB control. The chapter shows how nurses made sense of this gap and, making sure to keep in view the difficult position they were placed in, suggests why they often resorted to blaming and scolding patients. Ultimately, however, I show how TB is moralised, reproduces stereotypes of the poor and legitimises authoritarian nurse-patient relations in ways reminiscent of the apartheid era.

**Chapter 5** focuses upon the recruitment activities of SATVI's fieldworkers, which were concentrated in precisely the low-income regions that the government clinics struggle so much with. I show that there was a tension in the requirements of their work: to fill the trials, the fieldworkers had to follow the flows of material need (especially for money), but at the same time had to reconcile this with the principles of autonomy and 'greater good' that featured in the consent process. I show how the fieldworkers navigated community settings and dangerous gang territories and attempted during the consent encounter to make people feel valued and needed, simultaneously as research subjects and as people more generally.

**Chapter 6** focuses on how the role of participants in SATVI's trials was understood and enacted by participants and staff. It argues that, in the same moment that trial protocols were shaping people as standardised and commensurable scientific objects, on the ground it was the moral subject that was the all-important object of knowledge and intervention as both participants and staff brought their own beliefs, values and ideas of proper personhood to bear on the category of the human subject. The chapter oscillates between two symbolic associations: between TB and 'dirt' (dirty places, people and practices), and between SATVI and 'clean blood', a prevalent understanding of the trials which collapsed the distinction between object and subject. The chapter renders visible an emergent moral economy unfolding between these two poles, with people at once framing themselves as moral and respectable individuals while at the same time locating the ever-present figment of immoral personhood, the *skollie* or 'problem patient', in others. I reflect upon how the idiom of 'clean blood' differs from the scientific conception of participants' value, and also upon the symbolic capital, stability and possibilities for new life trajectories that are offered by trials in a context characterised by instability and unpredictability.

**Chapters 7 and 8** offer competing accounts of SATVI's role in the local context of health seeking and delivery viz. a viz. government clinics. **Chapter 7** takes the perspective of participants and shows how they constructed themselves as responsible, health-seeking individuals who have been deeply wronged by the government clinics. SATVI, I will show, was viewed as almost the diametric opposite of the clinics. Whereas the clinics were viewed as degrading and inhospitable environments in which they felt they were subjected to scolding, indignities and breaches of confidentiality, SATVI was perceived to be friendly and caring and confidential, treating them with dignity and respect and actively including them in the decision-making process. Consequently, while they understood fully that SATVI did not have the capacity to treat any diagnosed conditions, it was viewed as a preferable point of entry into the health system.

**Chapter 8**, by contrast, casts SATVI as it appears from the perspective of government clinic staff, which is one of extending their reach into 'difficult' community settings and control over elusive bodies therein. It focuses on the interactions between SATVI and the government clinic nurses at the point at which many participants were diagnosed with TB and thus referred to the clinics for treatment, especially in the frequent even that participants resisted the transition from participant to patient. Here the governmental stereotype of the irresponsible and elusive patient was reactivated and worked upon, and raised the question of whether SATVI was responsible for these participant patients and for how long. This final chapter serves as a sobering reminder as to the limits of people's abilities to cast off the structural violence that shapes them and highlights the magnitude of the challenges facing the health system in post-apartheid South Africa.

**The final chapter** revisits *Carina's Choice* to reflect upon the central themes of the thesis. This includes the significance of 'global' medical research in contexts characterised by precariousness, instability and abjection; the experiential dimension of

‘vulnerability’; and the particular moral economy that I found surrounding SATVI’s trials. I finally offer directions for future ethnographic research, both with SATVI and in the broader field of TB-related medical science.

# Chapter 2

## Field Site and Study Design

### SATVI and Post-Apartheid Worcester

SATVI is based at the Institute of Infectious Disease and Molecular Medicine at the University of Cape Town (UCT). Established in 2001, SATVI has grown from a small research group of just five, originally named the “BCG research group” to a large institute with a staff complement of well over 100 people (explored in Chapter 3). Its field site, where I conducted my fieldwork between August 2014 and 2015, is located 110km from Cape Town away on the premises of Brewelskloof TB hospital in Worcester, a semi-rural town in the Breede Valley sub-district of the Cape Winelands. The field site – or “the Boiler House” as it is known – incorporates a main office building (Figure 1), a number of vaccine clinics scattered around the hospital<sup>10</sup>, a satellite lab (the main one is in Cape Town) and a pharmacy. SATVI also has a large fleet of branded vehicles for conducting enrolment home visits, participant site visits, and transporting samples between Worcester and the Cape Town lab. The staff complement of the field site is around 65, including doctors (principal investigators), nurses, fieldworkers (referred to as clinical research workers [CRWs]), drivers, lab technicians, pharmacists and admin workers.

From its base at the hospital, SATVI has a wide scope of operations of approximately 40,000 km<sup>2</sup> and a study population of 350,000, which includes Worcester, other smaller towns and the numerous farms in the Breede Valley. Since the first trial, SATVI has enrolled well over 20,000 infants, adolescents and adults into TB vaccine trials and related studies over the years and this number is steadily rising. The majority

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<sup>10</sup> These vaccine clinics are isolated from the main hospital wards for the purposes of infection control. A description of how SATVI’s research spaces are arranged is provided in Chapter 2, which explores the social dynamics of capacity building.



of the institute's trial activities at the time of my fieldwork were concentrated in the town of Worcester itself, which has around 100,000 residents.



**Figure 1: SATVI's project office or "the Boiler House"**

Worcester, as with the Western Cape more generally, remains divided along racial lines despite the freedom of movement since the end of apartheid. The town is divided by a long road called Durban Street, which historically separated those labelled 'white' from 'non-white' under apartheid. North of the road is inhabited primarily by the town's more affluent residents, which includes the majority of town's white, primarily Afrikaans-speaking population (14%). South of the road, in the town's less affluent suburbs, live the majority of the town's residents, the largest proportion of whom are coloured, Afrikaans-speaking people (60%). Finally, on the outskirts of the town lies the primarily black township of Zwelethemba (25%), most of whom speak isiXhosa. There has been considerable movement and mixing between these historically divided populations,

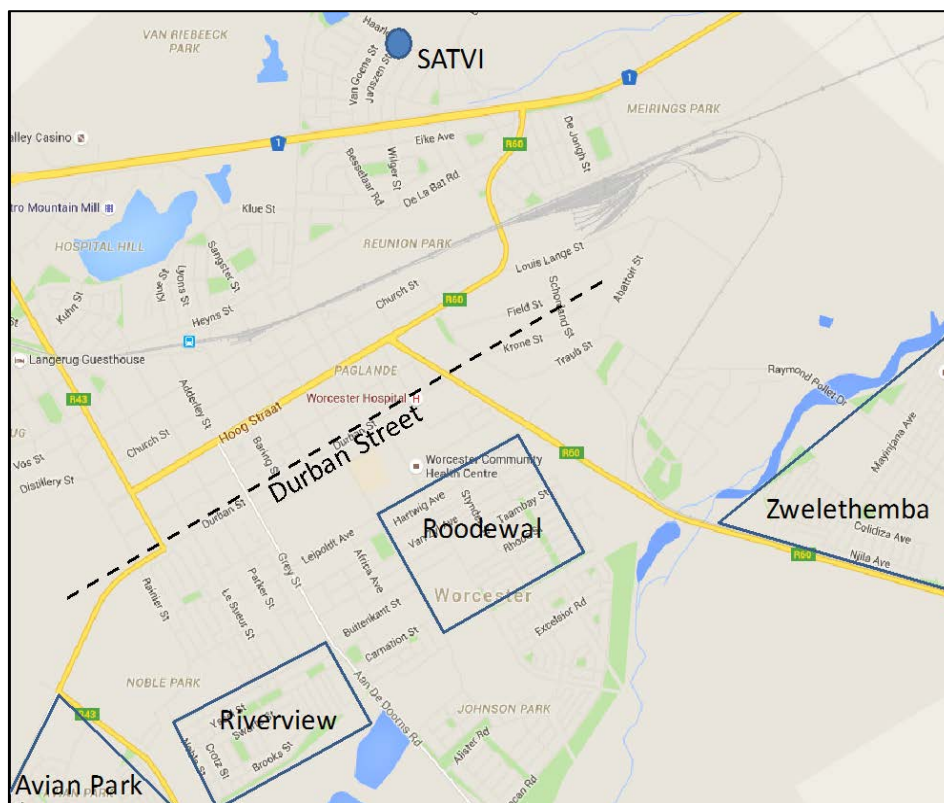
especially after apartheid.<sup>11</sup> Nonetheless, there remains a stark difference in the distribution of health and wealth between the north and south of the town. The majority live below the poverty line, there is a high rate of unemployment and many households entirely dependent upon meagre social grants (Appendix 3 includes socioeconomic indicators for the Breede Valley and the social grants available to South African citizens).

Brewelskloof hospital is situated in the north of Worcester in the middle of one of its wealthiest suburbs, ironically named Panorama. This is an odd place for such a hospital, given that TB disproportionately affects the poor. The hospital's location is partially because it predates most of the houses in the area and was chosen for being an appropriate location distanced from the town centre. The hospital and the residents of the suburb's large houses have a mutual lack of interest in one another, with TB circumnavigating the suburb and others like it with uncanny precision. Meanwhile, Worcester's low-income suburbs are home to one of the most severe TB burdens in the world, even by the Western Cape's standards, which has the highest burden in the country. Compion (2008, p. 28) observes that the Western Cape's TB burden is a "unique epidemic within an epidemic", one which is driven by a combination of "rapid urbanisation and poor housing conditions, poor nutrition, overcrowding, unemployment, a short supply of nursing staff and clinics, as well as numerous social issues like alcoholism, drug abuse and domestic instability" (see also Health Systems Trust 2004). Worcester is no different. In addition to high rates of chronic poverty, the town has the fourth largest gangsterism rate in the Western Cape, high levels of alcoholism and substance abuse and government clinics that are stretched to breaking point with the

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<sup>11</sup> For example, Zwelethemba has many coloured residents, especially in its poorest areas (usually because of migration and it being easiest to settle in Zwelethemba with little or no money). At the same time, many black people live in the primarily coloured suburbs. Moreover, many black and coloured people who benefitted most after apartheid live north of Durban Street.

volume of patients and prevalence of infectious disease. TB and poverty are particularly prevalent in the low-income suburbs of Avian Park, Roodewal, Riverview and the township of Zwelethemba. It is no coincidence that it is in these areas, too, where most of SATVI's recruitment activity is concentrated (Figure 2).



**Figure 2: SATVI's recruitment hotspots**

Known colloquially to local residents as the 'TB people', SATVI is a familiar presence in these areas of Worcester. In fact, having conducted many vaccine trials on a variety of age groups, it is not uncommon to find whole families who have taken part in a trial or are currently involved in one. Because of its humble origins as a group of only five individuals, SATVI is sometimes referred to by the institute's members as a 'family business'. However, today it is probably more accurately described as a family business in the sense of entire household participation. "SATVI – something for all the family", was the way one of SATVI's doctors jokingly put it.

SATVI is as large and influential as other research institutes that have been the focus of anthropological investigation (e.g. Geissler et al. 2008; Molyneux et al. 2013; Reynolds 2013). However, because of the comparative strength of healthcare in South Africa, SATVI, like many other medical research institutes working within the country, are able to lean more heavily on government healthcare facilities than some other locations in Africa (Barsdorf et al. 2010), where research institutes are often required to provide basic healthcare for participants and even their communities during clinical trials (Geissler et al. 2008; Geissler & Molyneux 2011). While SATVI performs regular diagnostics and health checks as part of the screening and two-to-three-year follow-up phases of vaccine trials, the institute provides *no* treatment for any conditions, TB or otherwise, that are picked up along the way. Rather, participants are referred to their normal healthcare provider, usually a government clinic, which is then responsible for further diagnostics and treatment (Barsdorf et al. 2010). SATVI is, therefore, highly dependent upon the government clinics when running vaccine trials, departing somewhat from the imagining of an isolated island of ‘global’ medical research operating independently of state structures. For this reason, in addition to involving participants and research staff in my project, it was important that I conducted research in the government clinics that SATVI works with.

## **Study Design**

The fieldwork for my PhD project took place between August 2014 and August 2015. Most of this time was spent in Worcester, where I lived for a year, but also with occasional visits to SATVI’s headquarters in Cape Town. The project builds upon previous research with the institute which was conducted for a month in June 2011 as part of an undergraduate honours research project and the same again in June 2012 as part of my Master’s research (Dixon 2012; Dixon 2013). As a result, when I started designing my

PhD research, I already had a preliminary sense of the lay of the land, which helped immensely with research design. More importantly, I already had a very good working relationship with Dr Michele Tameris, a senior research officer based at SATVI's field site who helped supervise my previous research projects. With Michele's assistance, I was able to navigate the labyrinth of scientific and ethical review boards to gain approval for the study. Michele is the official Principal Investigator on this project, an aspect of the research which will be discussed further under Ethics.

The only participants in my honours and Master's research were SATVI's research staff (although, following them around, I inevitably came into contact with many other people involved in the trials). This project, however, aimed to provide a more comprehensive and historically informed account of how SATVI featured in the lives of those affected by their long-standing programme and therefore engaged a much broader range of local stakeholders. This included three broad groups: SATVI's research staff (n = 40); vaccine trial participants (65 adults and 33 adolescents, n = 98); and government healthcare professionals (n = 20). Regarding the latter, I focused upon the healthcare facilities with which SATVI has worked most closely over the years. This included three clinics: Worcester Community Day Centre (CDC), Worcester's largest clinic near the centre of town; Empilisweni clinic, located in the Xhosa-majority township of Zwelethemba (where the opening vignette was set); and De Doorns clinic, a more rural clinic nestled between a host of farms approximately 20 km from Worcester. It also included the staff of Brewelskloof Hospital.

My fieldwork was conducted in the context of four main clinical trials, which I followed throughout the year. The first was a Phase I adult trial which I shall call the Adult Safety Trial. This trial involved 66 TB-negative, healthy adults (of which I interviewed 26) and was designed to test the safety profile of a vaccine candidate. The

second was a Phase IIb trial, referred to as the Adolescent Trial. The trial involved 990 TB-uninfected, HIV-negative adolescents (of which I interviewed 33), and was designed to test a vaccine's capacity prevent TB infection. The third was a Phase IIb, multisite trial, which I refer to as the Adult Efficacy Trial. It involved 3,500 TB-infected, HIV-negative adults in total (of which I interviewed 27), and was an early efficacy trial to prevent active TB disease. The fourth, the most sensitive study, was a Phase I trial involving HIV-exposed infants (i.e. whose mothers were all HIV-positive; I interviewed 12 of the mothers). While the protocols of the trials differed according to their participants and aims, their routines were all fairly similar. Therefore, Appendix 2 provides an overview of the structure of these vaccine trials, from screening to final visit usually two to three years later.

The overarching methodology used in this study is that of ethnography. SATVI has been highly supportive of qualitative research, and has even conducted a number of studies themselves, some in collaboration with applied anthropologists (Mahomed et al. 2008; Abrams et al. 2011). Nonetheless, it was a steep learning curve for both me and my informants to conduct ethnography in a setting where people are more used to the hypothetico-deductive methods of clinical trials (Bosk 2007; Bernard 2011). It has also been Michele's thankless task to rein me in from time to time when my ethnographic instinct to explore and follow up on findings began to go beyond the scope of the predefined study protocol (see Ethics section). That said, it has undoubtedly been worth it; ethnography has proved ideally suited to getting beneath the neatness of the forms, the seeming commensurability of values and the formal accounts of SATVI's work to uncover the 'messiness' of clinical trials on the ground.

The two research methods that I used within a broad ethnographic methodology were (i) participant observation and (ii) interviews (semi-structured and unstructured).

These featured differently in my research depending upon the social setting and who I was interacting with. Thus, in the following two sub-sections I provide some further details on how I gathered my data and how they added value to the project.

### **(i) Participant Observation**

Participant observation is designed to capture people's day-to-day routines and experiences, enabling the researchers to determine what people actually do as opposed to just say (Hammersley 1992; Bernard 2011). It was my intention to ground my account of SATVI's work in "thick description" (Geertz 1973) in order to foster an appreciation of the everyday realities within which clinical research is embedded. Because much of the participant observation took place in medical settings, the 'participant' in 'participant observation' strictly does not refer to my participation in medical practices but rather in the social dynamics of the setting: engaging in dialogue, asking questions, responding to questions – in short, not attempting to disengage from observed social phenomena unless contextually appropriate (Hammersley 1992; Bosk 2008; Bernard 2011).

Only SATVI's research staff and government healthcare professionals were directly involved in participant observation in the sense that I asked them as part of the informed consent process. The routines I engaged in were, firstly, going out into community settings with SATVI's fieldworkers as they recruited participants. Secondly, I observed the morning vaccine clinic sessions at the trial site – not the consultations themselves (which were conducted behind closed doors) but rather in the waiting areas, where the staff were trying to channel people into the right rooms and make things run smoothly. I also observed the research staff as they went about their routines (but not involving contact with participants), for instance doing the paperwork. Finally, I spent time observing the routines of the government clinic nurses, primarily in the 'TB departments'.

In consultation with Michele, we decided that it would not be appropriate, either pragmatically or ethically, for me to ask participants or patients to be the focus of participant observation. Nonetheless through spending time with research or healthcare facility staff, I inevitably came into contact with both. In fact, while I did not imagine being party to nurse-patient interactions in the government clinics at first, I realised quickly that because there were fuzzy boundaries between public and private in the government clinics regarding TB – for instance, the doors were almost always open and with up to three patients in there at once – it was very difficult to spend time with the nurses and *not* witness these. As we will see in Chapter 7, this methodological consideration is part and parcel of the reason why many people find government clinics so unpleasant and SATVI so attractive.

## **(ii) Interviews**

Almost all of the participants in my study were interviewed, sometimes two or three times in the case of the members of the research team I grew closest to. There were a number of reasons why interviews were a valuable complement to participant observation. Firstly, they allowed me to shed additional light upon the events I witnessed while observing. Allowing for a greater degree of reflection than is possible in the day-to-day hustle of participant observation, interviews not only helped me to understand what has transpired, but also enabled a deeper exploration of meanings, beliefs and attitudes (Greener 2011; Bernard 2011). Secondly, they offered a means of drawing out phenomena related to the project that are not within the scope of participant observation (e.g. history). Thirdly, it was the only method that it was appropriate to use with participants.

The majority of the interviews were semi-structured. One of the reasons for this was because the University of Cape Town's Human Research Ethics Committee wanted to have a good idea in advance of the kinds of questions that I would be asking people in



order to assess whether or not the line of questioning was ethically appropriate. By the time that I started the project, I had several interview schedules, each tailored to the different groups that I would be interviewing. While it is challenging trying to anticipate the questions that I wanted to ask before even starting the project, having these schedules turned out to be very useful. For especially in the case of trial participants and government nurses, interviews had to be made to fit around busy study visits and chaos of government healthcare delivery, which meant that the interviews were sometimes rushed and did not lend themselves to an unstructured interview format. The interviews with participants ranged from 15-40 minutes; with stops and starts, interviews with government healthcare staff were between 30 minutes and an hour and a half; and interviews with SATVI's research staff were anything from 40 minutes to two and a half hours. It was these interviews with SATVI staff that were more likely to be unstructured, especially follow-up interviews where all planned themes had been addressed.

During interviews with participants, an Afrikaans or Xhosa translator was always present, both for the consent process and for the interviews themselves. Through the project, I had the help of several different translators, some of them SATVI's fieldworkers when they had time to spare, other times with externally sourced ones whom I was able to find with the help of SATVI. The extent to which the translators needed to translate the proceedings varied immensely depending on the individual. Some informants were perfectly fluent in English but most struggled and on occasion switched between English and their home language; sometimes the entire conversation needed translating. Interestingly, it was not just matters of language in which the translators were highly beneficial. They played an important part in making participants feel comfortable, added to the conversations and often picked up on things that I simply missed. The translators are very much responsible for my development as an interviewer, as well as the

development of the interview schedules, for I had regular prolonged discussions with them between interviews about what had been said, the themes that were emerging and how we could improve. Invariably, I asked permission to tape record and transcribe interviews. In the small minority of cases where my participants did not feel comfortable with the use of a tape recorder, I took notes instead. Interview recordings were destroyed once transcribed.

### **Ethical Considerations**

This project was designed in accordance with the American Anthropological Association's (AAA) Statement of Ethics: Principles of Professional Responsibility (AAA 2012) and Anthropology Southern Africa's Ethical Guidelines and Principles of Conduct for Anthropologists (Anthropology Southern Africa 2005) These codes implore anthropologists to carefully consider the structural circumstances informing ethnographic encounters and, moreover, to remain aware that ethical conduct is a process that begins the moment research is conceived and continues after ethical clearance is granted. Ethical approval for the project was attained through three channels. Firstly, in Durham it received approval from the Department of Anthropology's Ethics Committee. In South Africa, the project went through UCT's Human Research Ethics Committee in the Faculty of Health Sciences. Finally, in order to conduct research in government healthcare facilities, I attained approval from the Western Cape Department of Health.

Conducting ethnography in medical settings is a challenge and one that has been debated fairly extensively (Bosk 2007; Molyneux et al. 2009; Macdonald & Spiegel 2013). The challenge stems at least partially from the different epistemological backgrounds. Medical research ethics procedures are designed with clinical trials and similar studies in mind, where everything that is going to be done can be stated in advance; its regulatory structure seeks to anticipate and control researchers' actions

without leaving any stone unturned. The inductive and exploratory approach of ethnography thus sits uncomfortably with medical research ethics, because it means placing trust in the ethnographer that they will behave ‘ethically’ in response to particular situations (Simpson 2011). Indeed, this is precisely the kind of relational ethics that ethnographers have shown that frontline clinical research staff must engage in on the ground (e.g. Molyneux & Geissler 2008).

In order to attain approval from University of Cape Town’s ethics committee, I had to make several methodological compromises. For instance, as discussed above, I had to provide detailed interview schedules in advance and state exactly where and with whom I would be spending time. I was, of course, more than happy to make these concessions and learned much about the rationale behind medical ethics through the fieldwork. Nonetheless, as mentioned above, Michele and I have had to work much out along the way. Michele, as the principal investigator, bore responsibility for any indiscretions I might have made and thus, on occasions, when I had my anthropology ‘hat’ on and wanted to go off ‘exploring’ Michele was the one to sit me down and have a long think about whether what I was proposing was consistent with protocol. Can I go here? Can I ask participants this and that? Can I speak to this person or that person? These were things which struck me as necessary and unproblematic at the time but which, in fact, required careful consideration to remain true to the study’s protocol. It was not lost on me that that participants in SATVI’s vaccine trials must have been going through a similar journey, contending with the trials’ protocols, wondering what was expected of them and how to comport themselves. This is something that I try to bring out in the following chapters.

In addition to the above considerations, below I detail how I adapted the major ethical tenets of human subject research to suit my project: (i) harms and benefits, (ii) informed consent, and (iii) privacy and confidentiality.

### **(i) Harms and Benefits**

Ethnography does not pose the threat of physical harm to participants in the way that, say, clinical trials might. Nevertheless, ethnography is an intensive research methodology, involving not only prolonged but also affective interactions between anthropologists and research participants (Hammersley 1992; Bernard 2011). This form of engagement has the potential to make participants feel uncomfortable or even distressed if conducted insensitively or without due consideration of participants' right to privacy.

Participant observation was the most intensive method used. Consequently, the time frames of participant observation were arranged in consultation with participants with the explicit aim of ensuring that they were comfortable with my presence at all times and felt empowered to alter or terminate any agreed upon time frames. Another potential source of discomfort I was on the lookout out for were questions during interviews that asked participants to relate beliefs, attitudes, meanings or experiences. I made it clear during the consent process that that they could refuse to answer any questions they did not feel comfortable answering, whether in the course of my participant observation, interviews or focus groups. In the event that the research drew out experiences that caused significant distress (for instance, regarding illness of a relative), I had the measure in place to refer participants to an appropriate counselling service. Fortunately, nothing of the sort occurred and most were comfortable throughout.

Participants were not remunerated for taking part, although South African health policy does permit this in certain circumstances where appropriate (Anthropology Southern Africa 2005). I did, however, almost invariably bring snacks and drinks with

me for participants during in interviews. In the case of adolescents, I made sure to bring sandwiches along. Interestingly, most of the adolescents did not eat or drink anything during the interviews but instead stashed them in their bags for later consumption and sharing back home. I do not believe this constituted any kind of ‘undue inducement’, and it felt the least I could do for giving me a portion of their afternoons.

## **(ii) Informed Consent**

Informed consent was elicited in accordance with the AAA’s Statement of Ethics (2012). All participants were made aware that they could interrupt or withdraw their participation at any time with absolutely no repercussions. Although not required by AAA (2012) in all instances – which holds that informed consent should be adapted to context – I did use informed consent forms (Appendix 4). This is because the project took place in a medical environment where consent forms are standard practice and is contextually appropriate. In addition, I treated informed consent not as a once-off event but rather as an ongoing process during which I will maintained an open-ended dialogue with participants.

In order to ensure that linguistic barriers did not impede the consent process, Afrikaans and/or Xhosa interpreters were used where necessary, and informed consent forms were made available in English, Afrikaans and Xhosa. In the case of adolescents, it was parents/legal guardians from whom consent was elicited, with the adolescents providing informed *assent* on a separate form. A final consideration for trial participants was that they were made fully aware that I was not a member of SATVI and that participation my project did not have any bearing on their clinical trial participation. Understandably, this was often a deep concern for participants who did not want to be interviewed.

### **(iii) Privacy and Confidentiality**

Assuring that participants' privacy was respected and that data remained as confidential as possible was a key priority for me. As was discussed above, ethnographic research methods are particularly intensive and it was therefore important to put measures in place to ensure that participants do not feel that their privacy is being intruded upon. Throughout the fieldwork's duration, all raw data remained confidential, with field notes and the tape recorder kept on my person and laptop password protected at all times while in the field. The only people who had access to the raw data were myself and my supervisors, including Michele. However, in order to protect employees lower down SATVI's organisational hierarchy, Michele, who is a member of management, did not have access to *any* raw data pertaining to SATVI's research staff. This was conveyed carefully to SATVI's research staff during the consent process, who I am sure would otherwise have worried that the information they imparted to be would be immediately shared with SATVI's management. Michele has acted as a supervisor in all other capacities.

The kinds of data that were kept as hard-copy during the project were field notes taken in the course of participant observation and notes taken in interviews where participants did not wish tape recorders to be used. Electronic data included typed-up field notes and interview notes, interview and focus group tape recordings, and interview and focus group transcriptions. During the fieldwork, electronic data were stored on a password-protected laptop and an external hard-drive. In all raw data, participants' names and identifying characteristics were removed. Moreover, after being transposed into electronic form, all tape recordings and field notes were destroyed.

In all publications and other outputs from this PhD project, the majority of participants will be assigned pseudonyms. Pseudonyms have proved tricky in the case of

certain individuals. It was only towards the end of the fieldwork that it was decided that it would be appropriate for SATVI's name to be used. But in doing so, for those with more unique roles, it is almost impossible to maintain their anonymity if anyone were to probe on the internet. Fortunately, these individuals are the higher-ranking members of the institute, and are happy for their names to appear unmasked. In the case of those lower down the institutional hierarchy, for instance nurses and fieldworkers, there are sufficient numbers that their identities can be protected through the use of pseudonyms.

## Chapter 3

### **“We Learned Research by Actually Doing It”: A History of SATVI**

In her ethnography *Scrambling for Africa*, Joanna Crane observes that, with the advent of “global health science” at the beginning of the 21<sup>st</sup> century, Africa went from being a continent largely excluded from advancements in biomedicine to “an area of central concern and knowledge production” (Crane 2013, p. 6). Previously ‘neglected’ diseases were suddenly hot on the global health agenda – especially malaria, HIV and TB – and with it, scientific opportunity to participate in the trialling of new biomedical products was rife, both for scientists in the global north and ‘local’ collaborators. A number of factors common to other developing world settings make African nations conducive to the conduct of clinical trials: infectious diseases are highly prevalent; ‘standards of care’ are lower; and populations are comparatively ‘treatment naïve’ – all of which enable smaller sample sizes and make it easier to demonstrate efficacy (Petryna 2009; Crane 2013; Geissler 2013). Under-resourced healthcare systems also make it more likely people will consent to take part (Biehl & Petryna 2013; Geissler 2014). Moreover, as Petryna (2009) argues, “ethical variability” in regulatory standards makes it possible to conduct trials in precisely these kinds of impoverished, under-resourced environments, whereas in the global north they might not be permissible (see also Angell 1997; Wendland 2008; Nguyen 2010).

At the same time, the conditions that make the continent scientifically valuable are precisely those in which it is challenging to conduct rigorous clinical science. In order to be inserted into the slipstream of ‘global’ knowledge production, researchers must conform to the scientific and ethical standards laid out in international guidelines,



especially GCP (see Chapter 1, p. 23). Nothing short of unfaltering compliance with these guidelines guarantees the reputability of results with regulatory agencies (e.g. the FDA) and journal audiences (Simpson 2012, p. 557). With the infrastructure, technology, expertise and oversight required to meet these standards often severely below-par in developing world settings, significant ‘capacity building’ and ‘community engagement’ initiatives are usually needed in order that local conditions can be leveraged to participate in the global knowledge economy. This includes building or upgrading research sites, clinics and labs; engaging local stakeholders; (re)training staff; ensuring supply lines and cold-chains<sup>12</sup>; and sometimes even establishing ethical review committees (ERCs) (Sariola & Simpson forthcoming; Geissler & Molyneux 2011; Crane 2013).

Today, Africa is punctuated with large medical research sites that have been around for years if not decades. They have considerable power and influence and hundreds of high-impact publications that have led to new products. Yet in Africa, as in developing world contexts more generally, we have relatively few sustained accounts of what goes into establishing such sites in the first place and how the conditions and social relationships for globally reputable clinical research are constructed and maintained. This chapter joins with a modest number of accounts which explore this from the perspective of ‘local’ collaborators, whose efforts to attract externally sponsored clinical trials are often driven by more situated concerns, for instance healthcare, social and economic development than their northern counterparts (Sariola & Simpson forthcoming; Petryna 2009; Petty & Heimer 2011; Crane 2013; Okwaro & Geissler 2015). It should be noted that the power differential between SATVI and its northern partners is not as pronounced as at some of the research sites explored by anthropologists in Africa (e.g. Okwaro &

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<sup>12</sup> The cold chain is a supply chain in which the temperature is rigorously controlled to make sure that the vaccine remains at the required temperature.

Geissler 2015). This is partially because academic medicine in South Africa has historically been well-resourced in comparison with the healthcare facilities upon which the majority of South Africans depend (Coovadia et al. 2009). Nonetheless, the researchers who founded SATVI needed to undergo a radical process of what Simpson and Sariola have referred to as “epistemic development”, that is, what they needed to learn and to accomplish in order for them to “participate, gain credibility and, indeed, compete in the game of global scientific research” (Sariola and Simpson forthcoming; see also Crane 2012). It is the social dynamics of this developmental process that I focus upon in this chapter.

More specifically, in this chapter I demonstrate that the history of SATVI is one of learning by doing. With so many international guidelines in circulation today, most influential among which is GCP, there always seems to be the assumption that the knowledge about how to conduct clinical trials, especially their ethical dimensions, is already in place, that it is fixed and requires only application. Anything that even slightly diverges comes across as irresponsible, if not raising the possibility of malpractice. Yet, while taking on the appearance of a closed system which covers all bases, GCP has travelled widely and been received and interpreted in very different settings to the Western contexts in which it was initially developed. From the perspective of local collaborators, international research guidelines do not simply fill a space that was until then left vacant, but have to be negotiated with pre-existing ways of doing things. Moreover, even local adaptations of research guidelines (e.g. South African GCP) do not offer all the answers.

When SATVI was established in 2001, funding for large clinical trials in Africa was on the rise, GCP was only just beginning to gain traction in South Africa, and the legacies of apartheid were still (and indeed still are) resonating loudly. Against this

backdrop, the researchers who founded SATVI committed to conducting a huge TB vaccine trial in a region with no previous exposure to field research with very little research experience themselves. By taking us into the microcosm of ‘the BCG trial’, I will show that the epistemic capacity for research was not secured in advance and then applied; rather it was an ongoing inductive, iterative and error-driven exercise that meant working with, through and often against the hard-set social relations of apartheid. As Dennis – SATVI’s first site manager and one of the main protagonists of this chapter – put the matter, “we learned research by actually doing it”. This chapter therefore contributes towards an arguably much-needed de-fetishising of GCP; to look beyond the obsessive drive towards rule-following in global health research by showing the ingenuity, creativity and experimentation that underlies one of Africa’s largest and reputable TB vaccine trial sites. This is, moreover, a useful point of entry into our exploration of SATVI’s trials, highlighting the origins and longevity of a number of the challenges and that have endured through to the present. These challenges include, most notably, conducting research in a context of medical paternalism and, secondly, maintaining the delicate line between research and care.

While most of this chapter is focused upon the BCG trial, the final section fast-forwards through the developments between the end of the trial and the present day. This is so that the necessary context is in place to turn to the events surrounding SATVI’s trials as they were unfolding during my fieldwork. It is unfortunately beyond the scope of this chapter to devote more attention to these subsequent developments, for every study and every milestone was an important part of SATVI’s growth and reveals something more about SATVI’s current shape. Nonetheless, the BCG trial was viewed as a rite of passage into the game of global scientific research and thus warrants detailed exploration. Let us turn to the relationship between two leading paediatricians, where it all began.

## **A Meeting of ‘Local’ and ‘Global’ Agendas**

SATVI began its life as an idea – a debate in fact – between two leading experts in paediatrics and infectious disease in the Western Cape. These were Professors Grant Hennessey and Maurice Kibel, colleagues at the Red Cross Children’s Hospital in Cape Town, the main paediatrics teaching hospital of the University of Cape Town (UCT). Professor Kibel, the senior of the two, had moved down from Zimbabwe in 1979 in order to fill a novel Chair in Child Health that had been established at UCT/Red Cross. The aim of this chair (one of three set up throughout South Africa in total, funded by the Stella and Paul Loewenstein Trust) was to bridge the gap, both metaphorical and spatial, between teaching hospitals and community-based medicine – “grassroots paediatrics” as Maurice referred to it. This attempt can be located within a broader historical trend (albeit a stunted and uncoherent one) towards the prioritisation of primary healthcare provision, involving the Gluckman Commission in the 1940s, Alma Ata in 1978 and the drive for equitable access to healthcare as the apartheid regime decayed through the 1980s and early 1990s. Grant arrived on the scene a couple of years afterwards, taking up a post at UCT/Red Cross under Maurice. Through the 1980s and 1990s they worked together closely as mentor-mentee, where they encountered a lot of TB and, in particular, childhood TB.

The debate that these professors were having during the late 1990s had to do with the method of administering BCG, which, given to infants at birth, was (and still is) the only available vaccine to protect against TB. The BCG has been shown to offer up to 80% protection against TB meningitis and miliary disease, but protection against ‘normal’ pulmonary disease is more variable, with protection waning towards the equator. As of the year 2000, Japan and South Africa were the only countries with large BCG vaccination programmes that still used the ‘percutaneous’ method of administering the

vaccine, rather than the intradermal method recommended by the WHO (Hawkrige et al. 2008). The percutaneous method involves a multi-puncture device that one applies pressure to, which drops a measured amount of BCG into the skin. The merits of this method are that it is cheaper and also has fewer side effects (Nicol et al. 2002; Hawkrige et al. 2008). The downside, however, is that there are more variables to consider, such as how much ‘pressure’ one should apply, and how much BCG would actually enter the skin. So how effective was it? Nobody really knew, and Grant and Maurice were at the forefront of the debates surrounding its relative merits (e.g. Nicol et al. 2002). In order to fall in line with WHO recommendations, South African national policy was transitioning around 1999-2000 towards the intradermal method, but an important condition that came out of these negotiations was that further research was needed. And it was then that Grant decided that it was time to do a large-scale clinical trial (phase IV) to compare the efficacy of the intradermal versus percutaneous methods of administration.

Involving around 12,000 newborns, such a study would dwarf any BCG study that had been performed since the mid-20<sup>th</sup> century. Where could this trial be conducted? And how would it be funded? Fortunately, Grant and Maurice, partially due to the latter’s mandate to get academic medicine more in touch with primary healthcare, had been providing outreach and support for a number of years in a semi-rural sub-district of the Cape Winelands called the Breede Valley. Practice included monthly ward rounds at the regional TB hospital, Brewelskloof, improving the standards of care in primary healthcare clinics, and also organising lectures and symposia for healthcare professionals in the region. In short, they were well known and respected by the district health authorities for the work they were doing. The Breede Valley had a number of attributes that made it highly suited for a large-scale BCG trial. Firstly, it has an astonishingly high burden of TB among the ‘coloured’ and ‘black’ communities, even by South African standards

(1,500 per 100,000 compared with the national average of 1,000 per 100,000). Secondly, it had comparatively strong public healthcare facilities, crucial for recruitment, record surveillance, and follow-up care for participants. Thirdly, it was a fairly discrete geographical area, with a stable rural population, and in easy reach of Cape Town (approximately 110 km). Because of Grant and Maurice, the district health authorities were “keen to get involved”, as Grant put it.

In terms of funding, there was a meeting of agendas. Grant originally sought funding from the WHO and UNICEF, but they did not have the resources available at the time. However, as Grant explained to me, “the world was talking about new vaccines because of the escalation of TB”, especially since the WHO declared TB a global emergency in 1993.<sup>13</sup> One US-based NGO very much at the forefront of the push for new TB vaccines was Sequela (which became Aeras), itself funded by the recently established Gates Foundation. At the time that the professors were seeking funds for the BCG trial – the year 2000 – Sequela was fortuitously looking for a site in the developing world to build capacity to conduct large, high-quality trials on promising TB vaccine candidates. Grant was, in other words, at the right place and the right time and “the rest was history”, as he put it. The agreement was that Sequela would fund the proposed BCG trial in order to build research capacity in the Breede Valley, after which Grant and his research group would turn their eyes to new vaccines. As Grant put it, the trial had four aims: (i) to answer a research question, (ii) to develop capacity for new vaccine research, (iii) to develop partnerships with the health services and (iv) to develop trust between themselves and the community at large. This is the story of how SATVI was established.

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<sup>13</sup> As discussed in Chapter 1, the BCG is not deemed sufficient as a self-standing TB preventative.

## Networks and Relationships

For the purposes of orienting the following exploration, the proposal for the BCG trial design was (very roughly) as follows. Pregnant women were approached at the Midwives Obstetrics Units in the Breede Valley – Worcester, Robertson, Ceres, De Doorns and Rawsonville – and asked whether they would like to enrol their baby into the study. For those that gave their consent, their babies were vaccinated with BCG at the hospital within 24 hours of birth with either the intradermal or percutaneous method of administration (which was randomised by week across all Obstetrics Units). Then, the babies were followed up ‘actively’ for three months for adverse events, with every baby being visited by the study team at least once. They were also followed up ‘passively’ for two years via their public clinics, where babies were seen regularly in their first years of life. This meant that in the event that a participating infant was brought to the clinic with signs of TB, the clinic nurses called the study team, who took them for an independent series of diagnostics (over a 48-hour period) that constituted the data for the trial. For those infants who developed TB during the trial, it was *not* SATVI’s responsibility to treat them, unlike in many trial sites in Africa where public healthcare facilities are much weaker (Fairhead et al. 2006; Geissler et al. 2008). Rather, they were referred back to their local clinic for treatment (or admitted to Brewelskloof children’s ward in severe cases). At the end of the trial, all of the data were analysed to determine whether there was a significant difference in the number of TB cases between those who had been vaccinated using the intradermal method and those that had been vaccinated using the percutaneous method.

Aside from the process of securing ethical approval (from UCT’s human research ethics committee), a huge amount of preparatory work was needed before the BCG trial could get off the ground. As reciprocation for the support given by the Department of Health, Grant started off with a small research team based in Cape Town running a

training programme in 2000 for nurses in the Western Cape on how to administer the BCG vaccine intradermally (which, as discussed above, was gradually being rolled out nationwide at the time). The motivation for this was that nurses were often administering it incorrectly, leading to adverse events. To this end, two of Grant's study nurses, Anita and Mary, visited all of the Midwives Obstetrics Units in the Western Cape, including Ceres, Robertson and Worcester, which was where the infants for the BCG study were going to be enrolled from. While this was for the good of healthcare in the region on one level, this also helped to ensure that, when the BCG trial got underway, the vaccines would be administered properly by the government facility nurses. Moreover, this initial work helped to build trust within the healthcare facilities for when the BCG trial started.

At the same time that this training programme was taking place, the work of setting up the trial site in Worcester began. Grant and Dr Toby Hardy – the doctor appointed to the post of medical officer for the BCG trial and who quickly became Grant's 'right hand man' – conducted much of the networking at the level of district upper management. This included liaising with the district manager, Dr Franz Kruger. Dr Kruger gave them permission to establish a site on the premises of Brewelskloof hospital, allowed them to admit participants to the hospital for diagnostics and gave them use of the old Matron's flat in the nurses' home in which to work. He also gave them progressively larger spaces in the hospital from which to work as SATVI expanded (to be discussed later). In addition to the trial site itself, Grant gained permission from Dr Kruger and other key players in the Department of Health to gain access to the region's government facilities (Midwives Obstetrics Units and clinics), and Dr Kruger sent directives to the facility staff to cooperate with the research team during the BCG study. As Grant expressed to me, without the support of the Department of Health, and Franz Kruger in particular, "we couldn't have got it [the BCG study] going".



While this networking at the upper-managerial level was crucial, there was still much work to be done developing relationships and trust ‘on the ground’. This was important because, as several people related to me, while some medical research had been conducted in the Breede Valley, this had mainly been conducted with hospital in-patients rather than at the primary healthcare level. Certainly, nothing on the scale that the BCG trial proposed to achieve had been conducted, which would involve many healthcare facilities and 12,000 infants in the region. “This was a major move into the community”, as Grant put it. Some of the most important work in this regard was performed by Dennis, SATVI’s first site manager. A lab technician by training, Dennis was from the area and had pre-existing relationships with the healthcare facilities in the region and their staff. Whenever I spoke about the formative years of SATVI with its staff, Dennis’s name almost invariably came up. For example, Toby, reflecting upon Dennis’s importance in SATVI’s early years, said:

Because he’s from that area, and he’s absolutely fluent in Afrikaans and English, he could make those connections and he was very well accepted...You could walk through Worcester and every second person would greet him.

It was Dennis who was regularly visiting the Midwives Obstetrics Units and government clinics, greeting and remembering people (“baby kissing”, as one person jokingly put it), setting up meetings with the facility managers to keep them informed of developments, and in general making sure that SATVI was an active and known quantity in the region right from the outset. He was, in many ways, SATVI’s first ‘face’ in the area. Moreover, with Grant’s blessing, he also gave several ‘gifts’ to the healthcare facilities, including putting fridges in the Obstetrics Units (which, during the study, would be used to store BCG vaccines but afterward the fridges reverted to ownership of the clinic), TVs and

other useful items. This relational work would become especially important once SATVI started relying upon government health facility staff during the BCG study.

### **SATVI's First Community Advisory Board**

It must be noted that, while SATVI's 'community engagement' activities were quickly aimed at the wider community, the lion's share of that work in the formative years involved mainly healthcare facility staff. This is particularly demonstrated by the establishment of SATVI's first community advisory board, which Dennis and Toby were charged with. Community advisory boards are the most common form of 'community engagement' and have received considerable attention in bioethical literature (Marsh et al. 2008; Pratt 2013; Kamuya, Marsh, et al. 2013). One issue that comes to the fore in relation to community advisory boards is: what is 'the community'? Moreover, is the advisory board representative of it? The ethical imperative underlying this is that the views of all stakeholders in research should have a say in how it is conducted and how it can be shaped to fit local values and cultural sensibilities. Dennis and Toby advertised the advisory board to the general public via a local newspaper. However, the overwhelming subscription was by healthcare workers. As Toby expressed this to me:

That [the community advisory board] was quite tricky because...the first one was very heavily dominated by people from the health services, so they were all happy to be part of this effort, and they were good people don't get me wrong, but ...You'd have the matron of here, the superintendent from there, et cetera. There weren't that many actually bona fide community reps. So, they were representing not the community but the health services!

In a similar vein, Dennis said to me: “the core of our community was the health facility people”. This very much reflected the relationship between healthcare staff and patients that had been inherited from apartheid, which had only elapsed six years previously. This was one in which healthcare staff were the ones who made medical decisions on the part of patients. As Toby put it, “in the old regime this is how healthcare worked: the doctors were right, the nurses were right, you did what you were told – very authoritarian”. As a result of this paternalism, the advisory board was very permissive when asked whether aspects of the trial were appropriate. For instance, Toby said to the board members, “we want to approach the mums when they’re pregnant, then visit them again at birth, et cetera – will this be acceptable? And as health professionals, some of them said ‘yes they’ll sign’. It was as simple as that”.

With so little input from lay community members, Dennis interestingly saw it as his responsibility to take on the role of the “community’s conscience”, as he put it. This was certainly for the BCG study, but he also maintained this self-appointed role throughout SATVI’s formative years. He looked carefully at research proposals, considered the risks and benefits, what was culturally appropriate and inappropriate and his input was fed into protocol designs. One notable example that Dennis related to me was an immunology sub-study that was proposed to take place within the BCG trial itself, involving HIV-exposed babies (i.e. with HIV-positive mothers).<sup>14</sup> Not only was the study incredibly sensitive (especially given that antiretrovirals were not yet available); it also involved regular blood draws from the babies. Dennis, in this case, was the one who considered the “agony and pain” of the children and the mothers who had to look on, limiting the volume of blood that the scientists were permitted to take at any one time.

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<sup>14</sup> This study was scientifically value in and of itself, like the BCG study. However, a subsidiary function was to build capacity for immunology, central to TB vaccine research.

This might seem like a highly problematic response to the challenge of a highly partial community advisory board, only adding another layer of paternalism onto the situation, another person claiming to know what is best for the ‘vulnerable’. However, what this shows, I believe, is that people will always find ways of acting ethically, of doing what they believe is morally necessary, even if the only place to turn seems to be one’s own virtue ethics, as was the case for Dennis. In subsequent years, the advisory board became considerably better represented by lay people. However, this was all built upon the lessons learnt during of these formative years and from grappling with challenges of representation in a post-apartheid setting.

### **Staffing and GCP Training**

A couple of months before the BCG study was due to start, other members of the field team were hired. The main appointments were three professional nurses: Lydia, a nurse with several years of experience working in TB in the Eastern Cape; Sophie, previous facility manager of Empilisweni clinic in Zwelethemba; and Lorna, a nurse from the town of Ceres. These nurses were to perform the bulk of day-to-day study tasks. While Dennis and Toby would take care of randomising the vaccines, the nurses were to: transport the vaccines to the Midwives Obstetrics Units; ensure the ‘cold chain’ was maintained; record the data; monitor the facility nurses as they administered the vaccines; follow up on adverse events, TB suspects and other illnesses; and perform certain TB-related diagnostics in the CV ward. It was thought at first that the nurses could also perform the consent process in the Obstetrics Units with pregnant mothers. However, this quickly appeared untenable. Thus, approximately twenty fieldworkers<sup>15</sup>, most of whom were previously HIV counsellors, were hired to perform the bulk of the informed consent

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<sup>15</sup> As discussed in Chapter 2, the fieldworkers are referred to at SATVI as ‘clinical research workers’. I use the more generic term for the sake of consistency with existing literature.

processes (although nurses did perform some), much like field workers who have been written extensively about in other African research contexts (Geissler et al. 2008; Molyneux et al. 2013).

Other members of the study team were drawn from four groups. Firstly, there were the nurses who had been conducting the training course all over the Western Cape, who were to stay based in Cape Town but serve as internal monitors for the trial and also help train the on-site staff. Secondly were the immunology team members, who were less important for the BCG study but central to the HIV sub-study and subsequent trials. SATVI's main laboratory was based in Cape Town; however, an on-site lab was established for less technologically intensive work. Thirdly was Brewelskloof hospital's paediatrician Dr Gilbert. While not directly a member of SATVI, he agreed to be part of the diagnostic team for infants brought into the hospital with suspected TB. Toby mentioned the following of Dr Gilbert and his contributions:

[Dr Gilbert] was an excellent resource, because even then he'd been at Brewelskloof for about ten years, so he knew paediatric TB on the clinical side backwards, and he would do the ward rounds, read the Mantoux, read the X-rays, and make a judgement. And he wasn't employed by us, so he could make an unbiased call whether this was a case or not.

(We will hear more about Dr Gilbert in Chapter 8; see also Dixon 2012, forthcoming regarding the diagnosis of childhood TB in research contexts). Finally, there were the various administration workers and support staff at the trial site and in Cape Town. This, in effect, was SATVI's first team. In the years that followed, SATVI expanded rapidly from this initial few to nearly 200. However, it all started with this small group of individuals.

A significant challenge for this first study team was that almost every member was accustomed to working in clinic and hospital environments, and almost none of them had any prior experience of conducting research. As Margaux, one of SATVI's first lab technicians, put it: "Most had clinical backgrounds as nurses or doctors, and had little knowledge of research, as research was a foreign concept, especially for this area". Toby made a similar point: "It was new for the nurses, but it was new for me as well". In order to train the team in how to rigorously produce clinical data, a great deal of training (and retraining) was needed. GCP was fairly new at the time, having come about in 1996, but in South Africa as elsewhere, it quickly became a key document in shaping the conduct and oversight of research practice (Petryna 2009:37; Simpson & Sariola 2012). Toby explained to me that, in the beginning, they relied largely upon external GCP trainers. But as the years went by, it was decided that it would be more economical to develop their own in-house GCP-accredited training and quality assurance department. This work was spearheaded by a research coordinator called Monica in collaboration with some international partners, particularly George Washington University.

What was interesting, however, was that while the impression I gained from SATVI's management was that everybody was trained in GCP before the BCG trial started, speaking to the nurses it became apparent that the training they received at the beginning was not couched explicitly in the language of GCP. Lydia said to me that:

We had a little bit of training, but not GCP training. Every Friday, we'd have something called 'supervision', where we'd go and meet with different groups of consenters, a different group each time...and this was the forum through which we taught them how to do the consents, with no knowledge of GCP... We needed to do GCP but we just didn't know it at the time.

GCP was more as a “buzzword from the US”, as Anita put it, which gradually took on pertinence as the trial went on and largely in *response* to challenges encountered along the way. Perhaps more importantly, every single person, regardless of their thoughts on GCP, expressed that they were all very much leaning ‘on the job’. As lab technician Margaux put this: “This was a tiny team, doing an enormous study, with absolutely no knowledge of clinical research. We were winging it”. Therefore, it is useful to dive straight in and highlight how, as with SATVI’s first community advisory board, this “enormous study” put everyone on a steep learning curve in which GCP functioned not so much as a clear set of rules pathing the way so much as a dim torchlight on an exploratory potholing expedition.

### **Trial and Error**

The first baby was vaccinated on the 23<sup>rd</sup> March 2001, to the relief and delight of the study team. This moment, and all significant enrolment milestones after that, were relayed to Grant in Cape Town and celebrated. Enrolment was very steady; in fact, as Toby said to me, one thing they certainly did not have a problem with was persuading pregnant women to enrol their baby into the study (cf. Reynolds et al. 2013). Of all mothers-to-be approached, “only a handful refused”, he explained. Nonetheless, the team encountered numerous challenges along the way that they had to deal with in a largely ad hoc fashion. Many of these had to do with the handling of vaccines, the maintenance of the ‘cold chain’, and the recording of participant and other relevant data – things which were crucial to ensuring the scientific success of the BCG trial and indeed for the broader effort to develop research capacity at the site (Petty & Heimer 2011; Crane 2012). However, the challenges that I focus on here, as they are the most relevant to the following chapters, are those relating to the face-to-face encounters between the study team and participants.

### **(i) Informed Consent**

The first challenge stemmed precisely from the realisation that so few mothers-to-be were refusing to take part, casting the spotlight on the consent process. As was discussed in Chapter 1, informed consent has a long history in medical research (see section entitled ‘globalised clinical trials’). Designed to uphold the bioethical principle of autonomy, informed consent involves the clear communication of information about research so that people can make rational, informed decisions to take part. The problem, similar to the one regarding the establishment of SATVI’s first community advisory board, was that the BCG study was being implemented in a context with a deeply entrenched culture of medical paternalism (cf. Simpson & Sariola 2012; Sariola and Simpson forthcoming). Lydia explained to me that, when SATVI’s team were enrolling participants from the Midwives Obstetrics Units, they were introduced by the facility nurses as researchers from the University of Cape Town and there was an intention for them not to resemble the government facility nurses. “They tend to say yes to anybody in a uniform”, as Lydia put it. But despite this, during Dennis’s first internal audit of the consent process, things went “horribly wrong”, as Lydia put it, with a paternalistic attitude underlying a consenters’ interaction with the mother.<sup>16</sup> Dennis recounted the incident:

When I was doing the monitoring for the consent, and this happened particularly in the Xhosa/black language consents...We listened to the nurse doing the consents, and you’d have someone translating it back to you. We were so, so intrigued and concerned, because we heard something to the effect of “you must do this study because it is good for you”. We’ve

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<sup>16</sup> Field workers performed the majority of the informed consent processes. However, especially in the beginning of the BCG trial when there were not so many field workers, nurses performed quite a few of the informed consents.



seen this on many occasions, it's a short-cut. They basically breeze through the consent form and say "you can read the rest later, but sign now because it's in your interests". And it was very much a thing of the command that the nurse had with their patients.

Sparkling a sudden realisation that something was fundamentally wrong, this incident was recounted to me as a sort of myth of origin for the 'need' for GCP, resulting more intense training and oversight of the consent process. As Lydia said, "GCP training got quite a lot more intense after that one. It was a turning point". Based on my experiences during fieldwork, I would suggest that this really was a turning point and that the research team were highly motivated to include participants and make them feel that it was their informed, autonomous decision whether or not to take part. More generally, as we will see in Chapters 5, 6 and 7, both participants and research staff came to value the more open and communicative relationship that was engendered by the research environment and the possibilities to which it gave rise.

It might have been the verbal component of the consent process that made for the best horror story as to what could go wrong with consent. However, speaking to the team, it became clear that they learned quickly that what mattered most to the regulators as evidence for conformity to GCP was the quality of *documentation* (Petryna 2009; Simpson et al. 2014). Mary, who had some prior knowledge of GCP as a trainer, did some more online research and found that they needed to look very carefully at the quality of data, case report forms, but especially the informed consent forms. It subsequently became Anita's job to regularly take a 10% sample of the consent forms, check that they were being filled in correctly and, in the event that there was an error rate of over 20%, they would do a wider audit and, if the need was found, Mary conducted further training with the staff. Reflecting upon the steep learning curve, Anita said, "It's completely

different today, we wouldn't dare...I mean if I think about it now, I'm quite horrified, it's just the way it was".

The following chapter, which focuses upon the activities of the field workers in community settings, explores the informed consent process in greater detail. The experiences of SATVI's first team just underline that GCP was not simply a stable source of guidance from the beginning but was learned on the job, an undertaking made more complex in the context of medical paternalism in which it was applied.

## **(ii) The Case Verification Ward**

To the dismay of the study team, they actually missed the suspected first case of childhood TB, because the public clinic nurses forgot to inform them and thus the baby was put on treatment before the study-related diagnostics could be performed. "There was no surveillance back then", reflected Lydia – referring to the surveillance department that was later developed to pre-empt this kind of occurrence. Despite missing the first TB case, others quickly followed and there was a steady stream of participants. Moreover, once the HIV immunology sub-study started sometime in 2002, they were going out and actively doing screening for TB in participating infants and many potential TB cases were identified this way. In fact, the volume of participants was enough that it outstripped what the hospital's general ward could handle.

Fortunately, the district manager Dr Kruger, with whom Grant was on good terms (discussed above), had an unused ward in the hospital which he allowed SATVI to make use of. Moreover, Lydia had been liaising with the hospital's matron for the purposes of training, and the matron actually 'lent' SATVI some nurses who worked in the study ward on their off days (which they were happy to do as they got paid overtime). The space was named the case verification (CV) ward, named after the purpose for which it was used, that is, diagnosing cases of childhood TB. It was designed and decorated by Anita and

Lydia, who ordered lots of things to furnish the ward including cots for the babies, beds for the mothers, mattresses and bedside trollies. They also made a play area, bought toys and painted a mural on the wall for the children, who were anything up to two years old when they came to the ward. Importantly, they sourced all of the items needed to furnish ward from local retailers. This not only helped consolidate SATVI's already positive relationships with the Breede Valley constituents by stimulating the local economy. It also turned out to be a good opportunity to spread the word about the BCG trial further, with several mothers-to-be agreeing to take part in the study as a result.

When they started admitting infants, they assumed at first that the mothers would come with food, nappies and other basics for both the baby and for themselves. However, they realised quickly how naïve this assumption was, especially given the poverty in which most participants lived. Thus, they had to ensure that the ward was equipped to sustain the infants and their mothers during their stay. A similar story was true of transport to the site. With most of the mothers being unable to get to the hospital by themselves, SATVI started with a modest two or three cars to fetch them from their homes and take them back afterwards. However, this quickly expanded and, in subsequent years, SATVI had around 30 vehicles that required fleet management. "Things kept coming up", commented Anita, leading to the rapid and largely ad hoc expansion of the site. This just demonstrates how many things are needed to run a large clinical trial in a resource-poor environment – things are not easily anticipated at the beginning. Fortunately for SATVI, perhaps, they had both the funding and the local support to satisfy the trial's large appetite.

### **(iii) Taking the Nurse out of the Nurse**

One challenge that emerged strongly during the BCG trial was the distinction between research and care, a subject which has received considerable attention in the social

scientific literature on clinical trials (Easter et al. 2006; Timmermans & McKay 2009; Wadmann & Hoeyer 2014; Zvonareva, Kutishenko, et al. 2015; Zvonareva, Engel, et al. 2015). Now with SATVI, the distinction between the two is, at least theoretically, clearer than in some research contexts, because SATVI's remit does not extend as far as providing treatment for diagnosed TB cases (see also Barsdorf et al. 2010). Nonetheless, during the BCG trial this became far more of a challenge than anticipated at the outset, and Dennis was, as with everything else, at the forefront of efforts to reconcile conflicting roles and imperatives relating to care.

Dennis explained to me that the use of nurses to conduct study data was an exercise in carefully selecting which skills were put to the service of data collection and which were to be filtered out. They needed the nurses to perform diagnostics, draw blood and record data – things which they had been trained to do – but at the same time they needed to put aside their instincts for caring. Dennis explained:

The work that they're doing now is not caring but rather it's data collection.

Maybe they draw blood, which isn't data, but it's still data isn't it... They're just using their knowledge of nursing to collect data the right way – that's why we use them.

The telling phrase he used to describe the task at hand was: “you have to take the nurse out of the nurse, you had to put the research nurse there”.

Dennis was aware from the outset that this would not be a straightforward undertaking, and that the divide between research and care had to be, as he put it, “continuously managed... It had to be engineered very subtly – you cannot just tell a nurse that you can't be a nurse”. Nonetheless, the task proved even more difficult than even he had imagined. This became especially clear during the HIV-exposed neonate sub-study. This study was, as Dennis observed, “a very sad study”, and because of its sensitivity

(discussed briefly above regarding the first community advisory board), there were incentives offered for taking part. This included ‘transport money’ (see Geissler 2011), a “little parcel of baby goodies” and also baby formula (since they wanted the mothers to avoid breastfeeding). However, Dennis recounted doing stock checking one day:

But when I was doing stock checking, I realised there was less than there should be. I realised that one of the nurses was giving more to the people than she should have, but because there’s only so much a baby can take it meant that they were passing it down into the community. So, I had to deal with this, because from an ethics point of view, and from an ordinary management point of view, we couldn’t have this going on. And she said to me, “[Dennis] but I’m a nurse, I can see the need, what must I do?” In that moment, I realised that you can’t take the nurse out of the nurse.

Dennis, in other words, realised that when it came to caring, his initial commitment to ‘taking the nurse out of the nurse’ was simply not possible. Indeed, the phrase ‘taking the nurse out of the nurse’ indicates the futility of the exercise, making one wonder what would even be left if it was achieved.

Even Dennis was, in several cases, left in doubt as to whether they could or should step back from getting involved in the care of participants. For example, they had one participating infant who was suspected of having TB and thus flagged as needing to attend the CV ward. However, when a study nurse went to collect the mother, it turned out that she had been thrown out of her house because it became known that she had contracted HIV, made worse by the fact she was not from one of the region’s ethnic groups. She came to SATVI destitute, with no house and as a result the study team “put her up” for a couple of days in the ward with her baby over and above the 48 hours that she would usually have stayed. In the end, she died in the ward. Dennis said to me it was these

incidents that begged the questions: Who is responsible? Who must be accountable? Dennis, reminding me that with so little community representatives on the advisory board he acted as the “community’s conscience” (see above), said to me that SATVI ended up arranging several funerals for infant participants who died during the study. This was because he felt that it was the morally appropriate thing to do in the circumstances.

The complicated relationship between research and care will, in various ways, be addressed in several of the following chapters (6, 7 and 8). There I will show that the new ways of being and relating that are attendant upon the production of knowledge do not simply amount to the stripping away of care. To the contrary, the experiences of Dennis and the nursing staff suggest that, in face-to-face encounters, one can never fully ‘take the nurse out of the nurse’ nor devise an a priori set of rules regarding how to manage the delicate line between clinical research and care.

## **Developments Since the BCG Trial**

By commencing our exploration of SATVI’s trials at the very beginning, with a small group of individuals who committed themselves to run a massive trial which vastly outstripped their initial experience and capacity, I have shown that much of the knowledge needed to participate in the global knowledge economy took place ‘on the job’. Yet a lot has happened since then as the research institute has moved towards the trialling of new TB vaccines. Indeed, much of the momentum driving the BCG trial forwards was the knowledge that this trial was only the beginning and that much more was soon to come. The years following the BCG trial was also “a time of great innovation”, as SATVI’s first epidemiologist put it. In the remainder of this chapter, I give a sense of these developments to put us in a position to pick up on the issues raised in this chapter as they manifested during my fieldwork. I divide this into three sections:

early phase studies on new vaccines; other preparatory studies; site development; and the landmark phase IIb infant trial.

### **(i) Phase I and IIa Trials**

At the time that Aeras (then Sequela) agreed to fund the BCG trial as a stepping stone towards trialling new TB vaccines, they had no particular vaccine candidates in mind. Rather, they were at the stage of ‘shopping around’ the various research institutes that were developing new TB vaccines to decide which to take forwards. The way that TB vaccine candidates are introduced into clinical testing is firstly through phase I and IIa (safety and immunogenicity) trials in settings where there is very little TB, which is because of factors related to the immune reaction to the vaccines. The UK, Europe or the United States are therefore appropriate locations. Subsequently, they are trialled in medium-prevalence countries, for instance Eastern Europe and West Africa. Only after this can they be trialled in high-prevalence countries such as South Africa, before finally being ready to commence early-efficacy trials (in high-burden countries).

Among the candidates that Sequela were interested in was MVA85A, a vaccine developed by Professor Helen McShane and colleagues at Oxford University. So promising was this vaccine candidate that the immune response generated by the vaccine was on “another order of magnitude” to other candidates, as Toby described it. Around the same time that the BCG trial was being run in Worcester, Professor McShane was conducting safety trials in Oxford and The Gambia. Thus, by the time that MVA85A was ready to be trialled in a high-prevalence country, SATVI already had most of the necessary infrastructure and expertise in place. In 2006, early phase trials began at SATVI. Involving between 35 and 50 participants in each trial, MVA85A was progressively trialled on healthy adults, then adolescents, then children and then finally infants. TB-infected and HIV-infected persons were also included these safety trials.

MVA85A was not the only vaccine trialled at this time, and SATVI in fact trialled 5 different vaccine candidates in 11 different protocols by 2012 (Hanekom et al. 2012). However, MVA85A, delivering on its initial promise, was the one which fared best in these early trials.

In terms of the ground-level conduct of these trials, several factors are worthy of mention and bear upon the happenings at the time of my fieldwork. During the BCG study, pregnant women were approached in antenatal clinics in the region to be asked if they would like their babies to be a part of the trial. By contrast, in these initial safety studies, SATVI started recruiting in community settings, thus commencing the active presence in Worcester's low-income suburbs that endures to the present day. Moreover, because these new TB vaccines were unlicensed products, SATVI had to obtain approval from South Africa's Medicines Control Council. This was a very difficult process, and Anita – internal monitor on the BCG trial and who became the regulatory affairs officer – explained that it took months of work and the help of an independent contract research organisation to get the first safety trial underway. One requirement of the Medicines Control Council was that participants be 'reimbursed' R150 per site visit (Appendix 2).<sup>17</sup> This is a standard in South Africa, and interestingly has not changed (e.g. in response to inflation) since 2005 when the first early phase trials got underway. As we will see, one of the things that SATVI is known for today in the Breede Valley is monetary contributions, and the reason that I put 'reimbursements' in inverted commas will become clear in the following chapters.

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<sup>17</sup> These 'reimbursements' were R150 per study visit (approx. £9 at the time of writing). These will be discussed further in Chapter 4.



## **(ii) Other Preparatory Studies**

In addition to testing the safety and immunogenicity profiles of new vaccines, many other preparatory studies needed to be conducted before efficacy trials could go ahead. Firstly, SATVI's researchers needed to determine the incidence of TB, that is, the probability of TB developing over a specific time frame. This is because the incidence determines how large a sample is needed to demonstrate a statistically significant level of protection over and above the BCG vaccine (the standard of care). The statistics for adults were readily available from the Department of Health. However, for adolescents and infants, this was not known precisely. Therefore, SATVI conducted two large-scale epidemiological studies over a two-year period, one involving nearly 4,786 neonates, the other involving nearly 6,363 adolescents, which would lay the groundwork for efficacy studies.

In addition to determining the incidence, these epidemiological studies were also used as a platform for a variety of other preparatory work. In the case of infants, there was need to conduct a study on how to best diagnose TB in efficacy trials. The diagnosis of childhood TB is highly challenging because unlike in older children, adolescents and adults, there is no single definitive test for TB (sputum culture is definitive in these other age groups). Therefore, they needed to find a 'diagnostic algorithm' that used a variety of tests and examinations as inputs and gave a yes/no as an output (Hatherill et al. 2010). In addition, the adolescent cohort study or "ACS", as it was colloquially known, was used to test the effectiveness of the quantiFERON blood test for latent TB, which was more reliable and pragmatic than the tuberculin skin test (requiring one rather than two site visits) but had never been tested in a high-prevalence setting. In the screening and follow-up for all subsequent trials, the quantiFERON blood test was used, and I am convinced that this is one of the reasons that SATVI has developed a reputation for being in the business of collecting blood from participants (see especially Chapter 6). Finally, these

studies were used to study participant retention, that is, how many were likely to drop out of trials. “We needed to see if they were prepared to go the distance”, as Dr Mahomed put this.

### **(iii) Site Development**

As was the case during the BCG trial, the rapid influx of studies and funding fuelled the rapid expansion of the site, occupying more and more spaces on the premises of Brewelskloof Hospital. Fortunately, the good relations between the hospital and SATVI endure to the present day, and the hospital has been highly generous to the institute in allowing it to flow into almost all unused areas. From being situated in the Matron’s flat during the BCG trial, SATVI then moved to the hospital Superintendent’s home around the back of the hospital. Then, when SATVI outgrew that, the only space that the hospital had left was an old boiler house, which was large but almost dilapidated – not to mention that it was believed to be haunted. Not deterred, they fully renovated the place and this is where the main offices remain today, with the vacated buildings becoming vaccine clinics for specific studies. The old superintendent’s house, for example, is now referred to as the Trials House, and has been used for adolescent studies in recent years, including the Adolescent Trial during my fieldwork (Figures 3 and 4).



**Figure 3: The Trials House (Outside)**



**Figure 4: The Trials House (Inside)<sup>18</sup>**

<sup>18</sup> Figure 2 depicts basic medical observations being conducted, for instance blood pressure, weight and height. Medical histories and procedures (e.g. blood draws) were performed behind closed doors to respect participants' rights to privacy and confidentiality.

What is interesting is that as SATVI expanded and the studies came and went, the buildings and clinics retained traces and memories of older studies. The Adult Safety Trial run during my fieldwork, for instance, was being conducted in the “ACS building”, named after the adolescent epidemiological study (literally, adolescent cohort study) that many of the research staff had fond memories of (Figure 5 and 6).



**Figure 5: The ACS Building (Outside)**



**Figure 6: The ACS Building (Inside)**

Moreover, the large clinic space in the main hospital building is no longer called the Case Verification Ward but rather, as of 2012, the Vaccine Trials Clinic<sup>19</sup>, and is the home of the Adult Efficacy Trial that was conducted during my fieldwork (Figures 7 and 8). However, almost every single member of staff still refers to it as the “CV ward”.

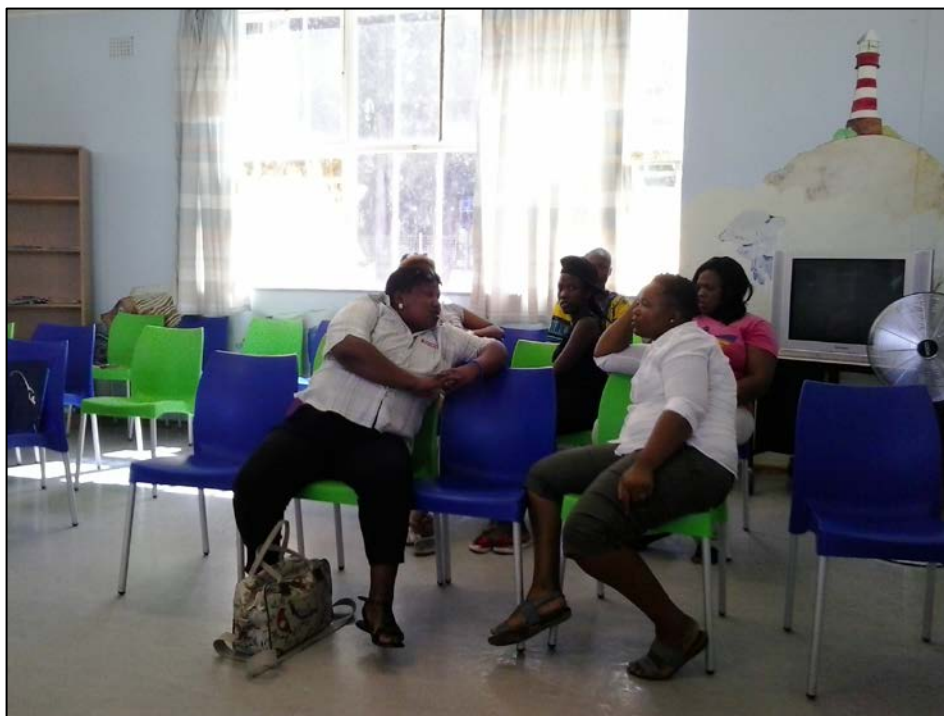


**Figure 7: The Vaccine Trials Clinic**

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<sup>19</sup> The name change is down to the fact that the ward is now used for screening, vaccination and follow-up rather than for ‘case verification’, a term that is specific to the diagnosis of TB in children which is a much longer process than for adults (Hatherill et al. 2010).





**Figure 8: The Vaccine Trials Clinic (Waiting Area)**

Finally, SATVI's main office space is colloquially referred to as "the Boiler House" (see Chapter 2, p. 47). This name has a double meaning: firstly, taking after its original purpose for the hospital and, secondly, describing SATVI's field site in relation to the Cape Town headquarters. Whereas the headquarters is where all 'thinking' happens, the field site is, at least theoretically, the place where things are simply 'done'. What I would suggest is that this second meaning is something that is most apparent to those working at the headquarters, from whose perspective a line between thinking and doing is sharpest. What this chapter and indeed the rest of this thesis draws attention to, however, is the creativity and innovation and that underlies the outward appearance of simple rule-following.

#### (iv) The Trial of MVA85A

By 2009, SATVI had all the necessary infrastructure in place to begin efficacy trials on new TB vaccines, with MVA85A first in line. In one of the most eagerly anticipated vaccine trials on a new TB vaccine since the BCG trials of the mid-20<sup>th</sup> century (Aronson & Palmer 1946; Rosenthal et al. 1961) approximately 2,800 HIV-negative infants were enrolled into a phase IIb (early efficacy) trial that ran between 2009 and 2012 (Tameris, Hatherill, et al. 2013; Tameris, McShane, et al. 2013). The excitement was palpable among the research team, not only the scientists but all those who had seen this vaccine emerge through its early stages as the most promising. It was sometime after enrolment had been completed that I emerged on the scene and conducted both my undergraduate (2011) and Master's research (2012). This involved mainly spending time with the field workers conducting home visits and with the nurses in the case verification ward, and my focus, at least towards the latter stages of my research (see Methods, Chapter 1), was on the ways that these staff balanced the fine line between research and care (Dixon 2013).

To the dismay of everyone involved – from researchers in Oxford and South Africa, to Aeras who partially funded it, to the field team – the trial failed to demonstrate the efficacy of MVA85A. Despite all its promise and the strength of the immune reactions that it generated in the early phase studies, this did not translate into clinical protection. The grief was experienced most profoundly by those, for instance my supervisor Michele and Helen McShane, who had invested so much time and even emotion in this vaccine. What was arguably even worse was that it was not entirely clear that the trial failed because the vaccine did not *work*. For it was suspected that the intensity of case finding among the study cohort might have picked up cases of TB *too* early, including cases that would have ‘self-resolved’. Thus, the worry was that the effects of the vaccine had been ‘washed away’. The problem was that there was simply no way that they could know,



leaving the researchers feeling desperately frustrated and with great difficulty letting go. As Toby, put it: “I was shattered when the MVA results came out...It was just so bitterly disappointing”.

Against the backdrop of and in response to this ‘failure’, when writing up my Master’s research, part of what I was trying to do was suggest the kinds of ‘success’ that went on beneath the failure. If the trial’s epistemological goals were undermined by its immediate effects, then this testifies to just how significant the trial, and SATVI’s research programme more generally, was as a public health intervention (Dixon 2012, Dixon forthcoming). This was a question that I wanted to take much further as part of my PhD research. My fieldwork commenced just as more trials were getting underway – for after all, there is very little time for mourning in the trials industry – and yet everyone was still feeling a profound sense of liminality. Having been caught in the momentum leading up to the anticipated trial of MVA85A, people were suddenly thinking: what have we been doing all this time? This was, in a sense, an ideal time to be asking people about the history of SATVI and to conduct an ethnography of the institute’s ground-level operations. I hope that the remainder of this thesis will help to satisfy this curiosity.

## **Conclusions**

In this chapter, I have described the multifaceted work that went into capacitating a comparatively ‘research-naïve’ healthcare landscape for the world’s largest contemporary TB vaccine trials. While GCP and other international guidelines are important for ‘good’ scientific and ethical practice, they tend to assume that the norms, values and practices that it enshrines are fixed in advance, a closed system that covers all possible eventualities in research practice. However, my aim has been to contribute to an arguably much needed de-fetishising of GCP by casting an eye back to a time when the guidelines were still gaining a foothold in South Africa and where, against the enduring

social forms of apartheid governance, SATVI's first team embarked upon a massive clinical trial with very little experience of how to do field research. From the perspective of these actors, there was not the comfort or stability of having everything prepared in advance and a simple application of pre-existing principles. Rather, learning to participate in the game of global scientific research was experienced as an inductive, iterative exercise in which error was as important a driver of growth and learning as success.

During the fascinating conversations that I had with SATVI's founding researchers, a number of them expressed that they had thought about writing the history of SATVI themselves. While a small number of publications have discussed the development of the site (Mahomed et al. 2010; Tameris 2010; Hanekom et al. 2012), they have not been able to provide the level of detail or depth of analysis that I have here. Perhaps the most important aspect of site development that these other publications were unable to convey, but which was spoken about most passionately by the first research team, was the pioneering spirit with which they entered the unfamiliar game of global scientific research and the sense of accomplishment that came from demonstrating that large field trials were actually possible in this particular setting. In the rush to produce the next ground-breaking scientific finding, these other successes often tend to fall by the wayside. It is my hope that this chapter does justice to innovation and endeavour that went into the founding of one of Africa's largest TB vaccine trial sites.

Aside from making a self-standing contribution to accounts of capacity building (Sariola & Simpson forthcoming; Petty & Heimer 2011; Crane 2012; Douglas-Jones 2012), the main purpose of this chapter going forward has been to highlight the origins of the themes and challenges that will emerge in the following chapters. Most important among these is the transition that SATVI's staff – who trained as doctors, nurses, HIV counsellors and more – had to undergo in order to become credible researchers. This

includes, firstly, the move from a 'normal' healthcare relationship, in which the purpose of interactions was to cure sicknesses, to a research relationship, where one had to 'step back' from care and into the distanced and disinterested position where people are scientific objects and the aim is the production of clinical data. Secondly, it includes a simultaneous power inversion from a culture of medical paternalism in which decisions were made for patients, to one in which the participants were active agents in the decision-making process. In the following chapters, one of the main aims is to show how these new ways of being and relating generated by the research environment provided novel possibilities for engaging with issues of health, wellbeing and respectable living in adverse circumstances.

## Chapter 4

### **A Disease beyond Reach: Clinic Staff Perspectives on the Past and Present of TB Control**

Dear Residents of Worcester,

TB is a big problem. It's a highly infectious disease and the main cause of deaths worldwide. Disobedient patients who refuse TB treatment are around in town and they infect the healthy, especially children and the elderly people. Currently TB is spreading like wildfire through Worcester. This means everyone can be infected with TB or die from TB. Our children and grandchildren might never have the opportunity to reach adulthood. Thus, all residents must immediately stand together to fight this evil and prevent Worcester becoming a ghost town.

(Sister du Plessis, TB nurse)

The above extract is from a flyer composed by a TB nurse at Worcester Community Day Centre, the largest of the three government clinics with which SATVI works most closely and in which I conducted fieldwork. Located just south of Durban Street – the long road spanning the length of Worcester that divided ‘whites’ from ‘non-whites’ under apartheid – (see Chapter 2, p. 48) – Worcester Community Day Centre (henceforth Worcester CDC) serves a population of around 70,000, primarily coloured, Afrikaans people living in the town's low-income suburbs. Driving through the clinic gates for the first time, the first thing that drew my attention was the long queue outside, with people either undergoing triage by a uniformed nurse or waiting to be called inside (Figure 9). More striking, however, was the wrought iron gate at the entrance that slid open and shut behind patients

as they were summoned, and the metal detectors and security searches that ensued just beyond. The fortified nature of the building served as a stark reminder of the neighbourhood that the clinic was in and its proximity to gang territories (Muller 2004). After asking for directions, I was taken the TB department, which consisted of two rooms – a treatment room and administration room – around the back of the clinic, outside which sat another queue of people (Figure 10). A peek through the wide-open door of the treatment room revealed two nurses working with separate patients, as well as a third patient taking what appeared to be a handful of pills at a sink in the corner. One of the nurses looked up and, expecting me, introduced herself as Sister du Plessis – a world-weary but highly experienced white Afrikaans nurse who, we will see, was driven to appealing to the residents of Worcester about a TB epidemic spiralling out of control.



**Figure 9: Worcester Community Day Centre**



**Figure 10: The TB Department**

Worcester CDC is the largest and most central of the three clinics. The second, Empilisweni clinic, is located on the outskirts of Worcester, just inside the entrance to Zwelethemba, the primarily 'black', Xhosa-speaking township of around 32,000 which it serves. The third and furthest afield, De Doorns clinic, is nestled between around two-dozen farms situated approximately 10 km outside of Worcester on the N1 highway, servicing a highly mobile population of around 22,000, many of which are only resident between October and March when their work is required by the farms. Residents both seasonal and permanent come from townships in Cape Town, the Eastern Cape, Lesotho and Zimbabwe among others. Between them, Worcester CDC, Empilisweni, and De

Doorns clinics cover approximately 70% of the Breede Valley's population of 167,000, with the rest divided among Rawsonville clinic and the smaller satellite clinics in the region. Across the three clinics, I observed and interviewed 20 clinic staff members, primarily nurses in the clinic TB departments, but also nurses in other departments (e.g. Child Welfare and HIV), facility managers, and the district managers working from Brewelskloof hospital.

This first of my ethnographic chapters hones in on the day-to-day work lives of clinic staff, particularly nurses, in order to describe the troubled post-apartheid healthcare landscape into which SATVI's trials have been inserted. During the time of my fieldwork, the regional Department of Health had made TB its number one priority because, with an increasing patient load and ever more drug-resistant cases emerging, it had outstripped HIV and AIDS as the disease that was placing the most strain on the clinics. Although TB presents difficulties on several fronts, the overarching one was what the district manager referred to as "the gap between the clinic and the home". This encapsulates, most pertinently, the dual challenges of (i) late diagnosis (contributing to the continued spread of TB) and (ii) 'defaulting' (patients starting but then prematurely stopping treatment). I will argue that this gap is historically determined by changes in the structure of the health system and a perceived dissonance between the theory and reality of how healthcare is supposed to function in post-apartheid South Africa. More specifically, the dissonance I identify is a between the ideal of free, rights-bearing citizens 'taking responsibility' for their health (by attending the clinics when sick), and a reality in which bad if not worse socioeconomic and epidemiological conditions often preclude this.

The pressure for managing this dissonance, however, was not evenly distributed but rather fell disproportionately on the shoulders of the nurses. The main ethnographic task of this chapter is to show how they experienced, attempted to make sense of and acted

upon the challenges of TB control and tries to suggest why practices of blaming, scolding and disciplining persist. Following a number of qualitative studies ‘writing back’ against the poor media reputation of nurses in post-apartheid South Africa (Walker & Gilson 2004; Hull 2009; Joyner et al. 2014), this chapter argues that such practices were not evidence that nurses are uncaring or attempting to assert their superior status over impoverished patients. Rather, I will suggest that these practices were tried and tested, albeit often desperate, attempts to provide care for people in an environment that made this incredibly challenging. At the same time, it is through the work of these frontline agents of the state that TB control constitutes a key site in which the structures of dominance that have endured through the democratic transition are reproduced. For in responding to challenges, they reinforce governmental stereotypes of uncaring, irresponsible – and in Sister du Plessis’ words, “disobedient” – bodies while simultaneously deflecting attention away from structural determinants of the TB epidemic. Going forward into the rest of the thesis, the sentiment that I wish to convey on the part of the government clinic staff is of sheer frustration and waning hope, a disconnect between clinics and the residents that they serve and a powerlessness to get a firm grip upon a disease that has been curable since the 1950s.

### **A Shifting Primary Healthcare Landscape**

During apartheid, healthcare in the Breede Valley was, as in the rest of the country, highly fragmented and inequitable. Aside from the minority who could afford private medical insurance (approximately 15%), the majority of the population were at least partially dependent upon the public healthcare system-. Disjointedly managed by the country’s fourteen separate health departments, the public health system was racially segregated, biased towards hospital-level care and the majority of services had to be paid for-(Coovadia et al. 2009). Of the clinics in which I conducted fieldwork – sizeable



buildings with large staff complements and offering a wide variety of services – only De Doorns clinic existed before the 1990s and even this clinic was considerably smaller during apartheid. With no nurses yet trained in primary healthcare (i.e. diagnosis and prescription), clinics during apartheid were oriented primarily towards preventative services (e.g. immunisations, antenatal care and health education) and dispensing treatment for certain diseases. The majority of curative services, meanwhile, including the diagnosis and management of TB cases, were run from the region's secondary hospitals where most of the doctors were located (Worcester Hospital and Brewelskloof), with outreach to the rural clinics. For the residents of Worcester, receiving medical attention meant queuing up outside of Worcester hospital from 3-4 am to get seen that same day; in the case of people living on farms, it usually meant waiting for the doctor to visit the clinic once every few weeks. In short, for the Breede Valley's poor, access to even the most basic of healthcare was severely compromised during apartheid.

Without deflecting attention away from the inequities of the public health system, for the purposes of this chapter it is important to note that experiences of being a clinic nurse during apartheid have been shown by a number of studies (including mine) to be often positive (Walker & Gilson 2004; Foster 2005; Hull 2009; Joyner et al. 2014). Firstly, with the bulk of curative services being rendered elsewhere, as well as the fact that many services had to be paid for, the patient load on the clinics was considerably less. There was also a feeling among many nurses that the profession was well-respected. Such respect was not only held by their (primarily coloured and black) patients, who as victims of the apartheid state were legally compelled to be subservient and obedient to healthcare professionals. Perhaps more surprisingly, they felt well respected and listened to by their superiors in the organisational hierarchy (Walker & Gilson 2004; Hull 2009; Joyner et al. 2014). Finally, and something which came out particularly strongly during

my research, was that nurses were an active presence in community settings, performing antenatal home visits, ‘defaulter’ tracing and health education. One thing that was especially valued by nurses was that, during home visits, one would not only see, for example, a baby, but also the other members of the household. Because of this, there was “very good communication with our patients”, as one nurse put the matter. Positive memories of nursing during apartheid are something that I shall go into more detail about later in this chapter, when we see how nurses used the past to highlight the troubles of the present. Suffice to note at this point that these are an important counterpoint to critiques of apartheid healthcare.

In 1992, with the end of apartheid imminent, the National Party ended the racial segregation of healthcare facilities, which was followed soon after by a radical restructuring of the health system in order to make healthcare more accessible to the country’s poor. The country’s fourteen health departments were consolidated into one national and nine provincial Departments of Health. With only 11% of the national healthcare budget being spent on clinic-based primary healthcare at the time of the transition, the Mandela government vowed to make primary healthcare, delivered through a district health system, “the cornerstone of health policy” (Coovadia et al. 2009, p. 828). Nationwide, 1345 clinics were built and a further 263 were upgraded (Coovadia et al. 2009), and in the Breede Valley specifically, Empilisweni was built in the early 1990s, De Doorns was upgraded in the mid-1990s, and Worcester CDC was built slightly later in 2001 to take the place of some of Worcester’s smaller clinics. Nurses were trained in primary healthcare, with the intention that many more curative services could be offered at the clinic level – including TB – which decreased the reliance upon (the very limited number of) doctors. User fees were scaled back and eventually eliminated (Foster 2005). Moreover, the Patient Rights Charter (1996) was introduced, which reflected the broader

post-apartheid constitutional emphasis on rectifying the wrongs of the past and ensuring that never again would people be subjected to the inequities and indignities of apartheid. The Charter spells out a wide range of rights including those to a full and comprehensive range of healthcare services, privacy and confidentiality, participation in health decision-making and the right to refuse treatment. It also includes the right to a “positive disposition” on the part of health workers, one that “demonstrates courtesy, human dignity, patience, empathy and tolerance”. Finally, the *Batho Pele* programme marked a shift in how patients were viewed, from subjects of responsibility to ‘clients’ or ‘customers’. The programme consists of eight principles which are designed to guide managers and healthcare professionals in correct practice, laying out an agenda for the reformulation of service delivery that is oriented towards customer choice and, importantly, enables patients to hold public servants accountable (Hull 2009).

The corollary of greater rights and more choice for patients, however, was a set of assumptions that patients would hold up their end of the bargain, as it were, which arrived in the form of patient ‘responsibilities’. Such responsibilities are spelt out underneath patient rights in the Patient Rights Charter (1996), and includes the responsibility to: take care of one’s own health; know their health services and what they offer; not abuse the health services; and comply with prescribed treatment regimens. However, it might be noted that this increasing emphasis on patient responsibility was happening at the same moment that the health sector faced a new wave of challenges through the 1990s and 2000s. The clinics, despite being more in number and better resourced, were quickly overstretched, due to a number of factors including: the removal of user fees; increased migration into and within South Africa; the rapid onset of HIV and AIDS (which in turn amplified TB); as well as increasing alcoholism, substance abuse and violent crime (Walker & Gilson 2004; Compion 2008; Coovadia et al. 2009). Moreover, whilst taking

a welfarist stance in relation to healthcare and social services, the Mandela administration bowed to international pressure to implement neoliberal-inspired macroeconomic policies that greatly limited government expenditure on healthcare and social services through the 1990s (Compion 2008), including the Reconstruction and Development Programme (RDP) in 1994 and the Growth, Employment and Redistribution Strategy (GEAR) in 1996.

Against the backdrop of these neoliberal-inspired macroeconomic policies, the increasing emphasis on patient responsibilities in the clinics can be situated within a broader discursive shift in responsibility away from the state and towards individuals and communities, with the development of effective community-based care being premised on “creating ‘partnerships’ with the private sector and civil society” (Compion 2008, p. 96). One manifestation of this was the cadre of ‘home-based carers’ that emerged in the early 2000s, who were funded by NGOs to take over much of the community-based work previously performed by nurses. This includes health education, the direct observation of TB treatment consumption<sup>20</sup>, ‘defaulter’ tracing and palliative care for the surging numbers of people with HIV and AIDS. However, as commentators have observed throughout the African continent, the deferral of responsibility for health and development onto impoverished individuals and communities only serves to legitimise the withdrawal of the state from certain core functions (Compion 2008; Biehl & Petryna 2013; Prince & Marsland 2014; Packard 2016). In South Africa, this deferral of responsibility could barely paper over the fact that the public health sector was simply ill-equipped to handle the surging numbers of patients generated by the nation’s deteriorating

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<sup>20</sup> In the years since TB was labelled a ‘global emergency’ in 1993, the WHO’s primary response to the epidemic has been to advocate the worldwide implementation of directly observed therapy, short-course (DOTS) through country-level National Treatment Programmes. Motivated by poor patient ‘adherence’ and substandard public health interventions, DOTS remains a central component of public health efforts to control TB.

epidemiological profile.

Perhaps unsurprisingly, patient experiences of post-apartheid healthcare have been shown to be often far from positive (e.g. Sokhela et al. 2013) – something which, as we will see in Chapter 6, constitutes one push factor into SATVI’s clinical trials. More significantly for the purposes of this chapter, several studies have shown how the nursing profession has undergone drastic and detrimental changes. With insufficient staffing and training in healthcare facilities during the 1990s, nurses bore the brunt of the increased workload that came from the influx of patients, which was only exacerbated by many nurses heading to the private sector or overseas (Foster 2005; Joyner et al. 2014). Nursing became increasingly “facility-focused” (Daire & Gilson 2014, p. ii87), as there were too many patients attending clinic facilities and community settings had become too dangerous to sustain the active presence that nurses had during apartheid. Workloads in the clinics were increased further with a growing emphasis on patient data collection in order to hold staff accountable, something which “becomes a source of intense anxiety [for nurses] and serves to exacerbate [their] workload” (Hull 2012, p. 629; see also Strathern 1996). All of these factors came together at the same moment that patient rights were improving and resulted in many nurses feeling a profound sense of lost status and respect (Walker & Gilson 2004; Foster 2005; Hull 2009; Joyner et al. 2014).

The high-intensity, facility-focused nature of primary healthcare documented by the above scholars is very much the reality that I encountered when I started spending time in the clinics in December of 2014. In fact, if anything, it was amplified in the case of the TB rooms, for as highlighted in Chapter 1, the Breede Valley has one of the most severe epidemics in the world (with an incidence of 1,500/100,000), and as I quickly found, the ‘TB rooms’ of these clinics are amongst the busiest of any South African healthcare setting. Without having even discussed TB control with the regional managers, it was

straight into these rooms that I began my excursion into TB control. In the following section, I thus begin ‘on the ground’, with a brief exploration of the daily rhythms of the TB rooms as I came to know them. Following this, I bring into view the particular challenges thrown up by TB in the Breede Valley and how these are connected to historical changes in the health system and epidemiological profile of the nation’s population since 1994.

### **The TB Rooms**

Located towards the back end of the clinics, the TB rooms were large, well-ventilated spaces that each contained a couple of desks, a treatment table, a sink, shelves full of TB medication, filing cabinets and with room to walk around. The corridors outside were lined with chairs or benches for patients to sit in while they waited, whilst their back doors led to the clinics’ backyards, which is where patients were periodically sent to cough-up sputum samples. Far from sombre and clinical, the TB rooms all bore the signs of familiarity and domestication, scattered with stationery, post-it notes, bags of pills bearing patients’ names, and often the radio playing in a corner. Working from their desks, two or, in the case of Worcester CDC, three nurses and an admin clerk, were the permanent fixtures of the rooms, working side-by-side throughout working hours. Doctors from Brewelskloof visited on a bi-weekly basis to handle more complex cases; but as the regional manager said to me, like the majority of clinic services TB is a “nurse-driven, doctor-supported service”. Most of the nurses were warm, friendly characters and allowed me to pull up a chair at the side of one of the desks from which I observed, asked questions and, when there was the chance, interviewed the nurses more formally.

From the second the clinics opened, the TB rooms were rife with activity, with people coming and going, manoeuvring around one another and trying to do many things at once. Most patients found their way to the TB rooms through attending the clinic after

experiencing signs and symptoms, and being sent to the right place following a process of triage at the front of the clinics. In the language of public health, this is referred to as passive case finding (PCF), which involves waiting for patients to come to the clinic rather than vice versa (active case finding [ACF]), and is premised upon patients recognising that they are symptomatic and promptly attending their clinic for treatment (Golub et al. 2005; Uplekar et al. 2013; WHO 2013). Other common paths to the TB rooms included: infants being sent from the antenatal department; HIV-positive patients being sent from the Infectious Disease room for TB screening; patients being sent from Brewelskloof Hospital (hospitalised TB patients who are well enough to return home); patients referred from other primary healthcare facilities; and referrals from SATVI (for the latter see Chapter 8). In the case of adults suspected of having TB, the first thing the nurses did was ask patients to produce two sputum samples outside in the backyard, which would be sent to the laboratory. The patients would be told to return 48 hours later for their test results. The process was a little more complex in the case of infants, because TB bacteria can only be detected in their sputum in 40% of cases (Moyo et al. 2012). As a result, they were tested for *latent* TB (via a Mantoux skin test) and then, if found positive 48 hours later, they were sent to Brewelskloof hospital for a chest X-Ray, which would be examined by a doctor to determine whether or not they had active TB disease.

For patients who had positive results upon their next visit, the treatment process started immediately. To give a sense of the volume of patients (and the ratio of nurses to patients), at the end of 2014 there were 741 people being treated for TB at Worcester CDC, 393 at Empilisweni and 389 at De Doorns (which is only slightly below the Breede Valley's incidence of 1,500/100,000). Upon diagnosis, the nurses started a 'TB folder' for each new case. Taking anything up to half an hour – “and every other one is a new case”, as Nurse Matthews at Worcester CDC said wryly – starting a TB folder involved

taking a clinical history, making basic observations and collecting demographic information. It also involved an HIV test. In fact, such was the co-infection rate that a diagnosis of TB was almost equivalent to a diagnosis of HIV (82% coinfection at Worcester CDC and, although I did not obtain statistics for the other two, the official figure for the region and country is 60%). Throughout their treatment, patients would have multiple appointments in the TB room. For the first two months of treatment, many people would come to the TB room *every* day to be observed taking their medication (i.e. DOTS). Aside from this, patients would have a sputum check at the two-month mark, four-month mark and at six-month mark. For many, this would conclude their relationship with the TB room and its nurses, and they could either stop attending the clinic or, in the of case patients needing ARVs, they would be referred to the Infectious Disease room for management of their illness.

### **“It’s the Ones that are Out There”**

When I started spending time in the three clinics, I was quite taken aback by the sheer volume of patients moving through the TB rooms day after day, month after month. It was one thing hearing that the Breede Valley has one of the highest burdens of TB in the world; it was another to see what that actually looked like in the form of patients attending the clinics and the amount of work that this entailed for the nurses. However, when I related this sentiment to the head of Worcester CDC’s TB room, Sister du Plessis, she looked at me with an ‘oh please’ sort of expression and said, in a turn of phrase that would stay with me throughout my fieldwork, “the ones that come here aren’t the problem; it’s the ones that are out *there*” (her emphasis). This she said while pointing in a southerly direction out of the clinic and towards Worcester’s low-income suburbs.

By “the ones that are out there”, Sister du Plessis was referring to those people who were sick with TB and either not aware that they had a life-threatening disease or were



unwilling or unable to attend the clinic to receive medical attention. One kind of TB case this included was those people who had been infected with TB, had subsequently developed active TB disease, but were yet to be diagnosed and treated. This meant that they were highly infectious and, because of the overcrowded and impoverished living conditions in which much of Worcester's population lives, likely to spread the disease to others (Compion 2008; Bynum 2012). I was speaking one morning with the district primary healthcare manager Dr Van Zyl, who expressed to me the futility of the situation: "You have this reservoir of infected people who just keep on getting the disease, which is compounded by the HIV problem. So they keep getting disease, and then infecting more and more people". Moreover, the prevailing opinion among the TB room staff was that those who were sick consciously avoided coming to the clinic until they could function no longer without medical attention (we will see the reasons as to why this was the case later on in this chapter). As Sister Louw of Empilisweni's TB room aptly put the matter: "the ones that come here are the ones that are really sick. They don't come here until they are skin and bones".

The thought of undiagnosed cases "out there" was certainly a source of concern for the clinic staff. However, a far more persistent source of frustration for them were patients who were diagnosed with TB, had commenced treatment but interrupted their treatment or stopped it altogether before the regimen was complete. This is widely referred to in high burden regions as 'defaulting', with people who default being referred to as 'defaulters'. The appropriateness of this terminology has been hotly contested (Farmer 1998; Ditiu & Kumar 2012), a point to which we will return shortly. However, it is referred to, the premature discontinuation of treatment is highly dangerous both for the individual and from a public health perspective. Missing even a few weeks of treatment runs the risk of developing multi-drug resistant TB (MDR-TB), which includes those who

have become resistant to at least rifampicin and isoniazid, the two most powerful first-line drugs (Bynum 2012; WHO 2016). The treatment regimen for those diagnosed with MDR-TB is much longer (up to two years), involves more toxic second-line antibiotics as well as a period of hospitalisation in many cases (at Brewelskloof, in the case of patients in the Breede Valley). Moreover, unless adherence is scrupulous for the entirety of the regimen, MDR-TB can easily become extensively drug-resistant TB (XDR-TB) (resistance to a number of second-line drugs). The protocol for XDR patients is that they are hospitalised at Brooklyn Chest Hospital in Cape Town for a minimum of three months – or at least until they are no longer infectious – but usually longer. The public health concern for both MDR-TB and XDR-TB is that these drug-resistant strains can be passed onto others, meaning that even without being non-adherent themselves, some people have to bear the consequences of those that have.<sup>21</sup>

With the consequences of non-adherence being so extreme, two other groups of health workers were crucial to TB control in the clinics. One of these was the clinic counsellors. Each clinic had two counsellors, whose job it was to, firstly, to help patients go through the difficult process of coming to terms with their illnesses and not only TB but also HIV and numerous other conditions. Secondly, and especially in relation to TB and HIV, their job was to instil in patients the importance of adhering to medication and to speak to those who stopped taking their medication. The other group of health workers were the home-based carers. Funded by the Boland Hospice (an NGO located on the premises of Brewelskloof hospital, near SATVI's offices), each clinic had about ten home-based carers assigned to them to perform a variety of tasks including: taking TB medication to those who were unable to attend the clinic, 'contact tracing' (locating

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<sup>21</sup> The cure rate for XDR-TB is extremely low. O'Donnell et al. (2013) found in a study among XDR patients in KwaZulu-Natal that 22% of patients were cured or successfully completed treatment.

individuals in TB patients' houses, especially infants, who should come to the clinic for screening) and 'defaulter tracing' (locating TB patients who had not been taking their medication). As Anna, one of SATVI's nurses who had previously worked at the clinics, said: "they [the home-based carers] are the length of the nurse's arm", and performed the overwhelming majority of community-based healthcare tasks on behalf of the clinics. Each morning, the carers would come into the TB rooms to collect names, addresses and treatment, and sometimes assist with other tasks around the TB room, such as counting-out pills. Empilisweni was by far the busiest, and on one occasion no fewer than ten people were in the TB room at once, including nurses, patients and home-based carers.

In spite of the work of the counsellors and home-based carers, the rates of non-adherence were incredibly high and had only been getting worse in recent years. As Sister du Plessis said to me: "the defaulter rate, it keeps getting higher and higher". The defaulter rate at all three clinics was about 20% and, at the time of my fieldwork, there were 6 MDR patients at De Doorns, 14 MDR and 1 XDR patient at Empilisweni, and over 30 MDR patients and 3 XDR patients being treated at Worcester CDC. The nurses pointed out that among these, a high proportion were gangsters or ex-gangsters, who they pointed out to me by drawing attention to the gang tattoos along their arms. It is against the backdrop of a frustration about the patients "out there", whose presence was experienced primarily as an *absence*, that tensions often boiled over. It was a daily occurrence that scenes of the following sort took place in the TB rooms...

Sitting with Nurse Jacobs in Empilisweni's TB room on a Wednesday morning in December 2014, a young woman slinked into the room holding a baby who was coughing profusely. Nurse Jacobs was aware of this particular baby and was immediately very cross with the woman, who was not the baby's mother but rather someone sent in her stead. She was cross because the baby had been brought to the clinic the previous Friday and,

after a scan at Brewelskloof, had been found so sick by the hospital's paediatrician Dr Gilbert that the baby needed to be promptly hospitalised. The mother was supposed to bring the baby to the clinic the following Monday morning to be admitted to the hospital, but had not showed up. Now, having sent the baby several days late with someone else (the mother's presence was required), Nurse Jacobs lost her cool. She said to the woman – who was sitting very defensively and not saying a word – that if the mother does not bring the baby in personally tomorrow she is going to send her to the clinic social worker. In fact, at that moment the social worker happened to walk into the room for other reasons, and Nurse Jacobs pointed and exclaimed, “look here's the social worker! The baby is sick, she's coughing all the time and she [the mother] knows it”. Nurse Jacobs said “thank you” to the woman and then looked down at her desk as if to say, “you are dismissed”.

Similar events occurred in Worcester CDC almost every day I was there. I arrived at the clinic one day to find Sister du Plessis on the phone to a patient with XDR-TB (the most dangerous form of the disease) who had been released from Brooklyn Chest Hospital to attend the funeral of his wife, but was supposed to return to the hospital soon afterwards to continue his rehabilitation. However, he had now been out of the hospital for a month and had apparently decided to stay out. At the time that Sister du Plessis had managed to contact him by phone, he was busy setting up for his son's birthday party. For obvious reasons, this deeply upset Sister du Plessis; the possibility of a large group of children being infected with XDR-TB did not bear thinking about. But this was a very real possibility and, as a result, Sister du Plessis threatened the man with all sorts, including calling the police. This episode was followed shortly after by an incident where the clinic had managed to summon an MDR patient to the clinic who had been off medication for a number of weeks. However, he had promptly changed his mind about being there upon arriving at the clinic, excused himself to go the toilet, and quickly

disappeared not to be seen again during my fieldwork. It was in one such moment of frustration that Sister du Plessis said to me:

You can't be nice to them. If you give them the pinky [little finger] then they will take the whole hand. Some of the sisters try to be nice to them but it is only me that will give them *skel* [to scold, or have strong words with]. Nobody likes me here. Only God loves me [she points upwards to the heavens]! But I don't worry, I'm not here to be nice I'm here to do my work.

### **Nurses and TB Discourse**

As highlighted above, the assumption written into the Patient Rights Charter (1996) was that, as patients were afforded greater rights in relation to healthcare, they would fulfil their end of the bargain and 'take responsibility' for their health, including complying with the protocols of the clinics. That individuals and communities would shoulder a greater burden of responsibility was, indeed, part of how primary healthcare was envisioned to function and what it was funded (and not funded) to do. But what these vignettes and Sister du Plessis' subsequent comments show is that, from their perspectives, there is a clear dissonance between the way in which rights-bearing consumers of healthcare were supposed to behave in the 'new' South Africa and the reality which the nurses were confronted with day-in and day-out in the TB rooms. Indeed, as we can see from the above, it frequently reverted to quite heated confrontations between nurses and patients.

Social science literature has drawn attention to the ways in which the language of patient responsibility – and similar terms like 'defaulting' and 'non-compliant' – have functioned to legitimise the blaming of impoverished individuals for their own treatment 'failures' (Farmer 2000; Compion 2008; Harper 2006; Harper 2010). In this, however,

healthcare professionals are often peripheral figures or cast as willing participants in harmful discourse. Indeed, in South Africa nurses have a terrible reputation in both academia and media for scolding and degrading patients – perhaps understandably, given how the above vignettes appear at face value. But rarely is a more critical gaze of the sort leveraged to vindicate patients passed through the health system and its workers to see what kinds of pressures and structural violence they are subject to. This is why the burgeoning body of literature responding to the condemning portrayal of nurses in South Africa is so important (Walker & Gilson 2005; Foster 2005; Hull 2009; Joyner et al. 2013). While I ultimately concur with the above social scientists regarding the harmful nature of TB discourse, I believe it important to counter unproblematic blame placed upon frontline healthcare staff by drawing attention to the challenges they faced and how they experienced, made sense of and acted upon them. Staff struggles revolve around the primary challenge of TB control highlighted above, which district primary healthcare manager Dr Van Zyl broadly referred to as “the gap between the clinic and the home”. Several themes emerged during my time with the clinic nurses, which will be addressed in turn: isolation and accountability; patient responsibility and blame; and nostalgia for the past.

### **(i) Isolation and Accountability**

One of the most frustrating facets of life as a TB nurse was not only that they were working on the frontline of one of the most challenging diseases to manage. It was that nobody seemed to appreciate the strife they were going through. As mentioned above, the TB rooms were around the back of the clinics at one remove from most of the other departments. The feeling among the TB room nurses was that none of the nurses from the other departments wanted to learn how to work in the TB rooms-. As a result, once assigned to the TB rooms they were largely stuck there and, moreover, denied the rotation

around the clinic that was standard practice throughout the rest of the clinics. Sister du Plessis, suggested that it was the infectious nature of TB and the poverty of TB patients that were the main reasons for this resistance among other nurses:

It's an infectious area...They are afraid that they'll get TB...And I think it's because there is not enough information. Look, the staff say they can't help us because they don't want to know what's going on here. Then I told Sister Olivier, if they don't come and see what's going on here or come and work here, they will never know what is going on here, right? Look, for the people who come here it's a social problem: they're not so clean, they smell, you understand? It's not everyone who will work with that type of patient.

Sister du Plessis here reveals an honest and uncomfortable truth about TB: that TB has heavy symbolic associations with notions of 'dirt'. Kate Abney (2011), in an insightful thesis entitled *Whoever Said a Little 'Dirt' Doesn't Hurt?* has written at length about this symbolism and how it contributes to the stigmatisation of TB patients. The association between TB and 'dirt' will be a recurring theme in this thesis and explored in most detail in Chapter 6 (where I will also discuss the association between SATVI and 'clean blood'). Suffice to say at this point that, for Sister du Plessis, the 'dirtiness' of TB patients was one reason other nurses do not want to work with them. Moreover, it is precisely because of an ethical concern for patients and the danger of alienating them further that almost none of the nurses I encountered wore masks, thus adding to the risk of being infected.

The facility manager of Worcester CDC, Sister Pienaar, explained to me the logic behind the differential staffing of the TB rooms:

Currently, there is a big, big issue with the staffing at TB. They are very frustrated there. At the end of the day we want every sister to do everything.

We want to rotate them. At first we rotate them on a quarterly basis, but we found out it's better to put a person in the TB or chronic department for at least one year so that they can build a kind of relationship. But at the end of the day we said to each other, we mustn't change the staff in the TB room. We must rather let them stay stable, the same people doing the job all the time. But what we are trying to do, we are trying to get sisters, one at a time, to learn also about TB.

There was, in other words, a tension between wanting to rotate nurses to ensure that they had a comprehensive skill-set, on the one hand, and needing a higher degree of continuity in the staffing of the TB rooms, on the other. This understandably came across as a lack of fairness on those who were assigned to the TB room and unable to leave.

Worse than a feeling of being isolated in the TB rooms was the belief that that managers, both in the clinic and at district level, paid much attention to the statistics without actually coming and seeing what things were like in the TB rooms. This reflects the increasing incursion of 'audit culture' into the domain of healthcare provision in post-apartheid South Africa (Hull 2012; see also Strathern 1992). The result was that the nurses felt they were being unjustly held accountable for the high 'defaulter' rates and poor treatment outcomes despite doing everything in their power to ensure that patients returned time and again to the clinics. Sister du Plessis related to me the troubling journey of self-doubt that she went through when the 'defaulter' rates began to skyrocket around the time that she began working in TB in 2009:

Sister du Plessis (dP): I don't know really, but it was very good. And when I started here there were also statistics on the wall, and most of the time, a hundred percent, a hundred percent. When I came here it fell, and I think oh, me the problem, right?



Justin (JD): I'm sure.

dP: But I do it right. I also say that is the real thing. And that's what I told Dr [Van Zyl] when he phoned last year in November about a patient, and he was very angry. So I said, doctor, TB is a bad problem in Worcester at this clinic. The default rate, it's going higher and higher. And I don't think they realise what a big problem it is, because you talk and talk...

JD: The doctors.

dP: Ja, and also the operational manager, because they don't come here so often, and now they realise when we talk. I asked Dr [Van Zyl] that he must come and have a look here. Then he was here last week, but now I think they realise how many patients are here.

As my fieldwork went on, there was a growing feeling among the TB nurses, as hinted in the above passage, that the clinic managerial staff were becoming increasingly aware of how out of control the TB situation was. This was, in large part, what prompted the Department of Health to place renewed emphasis on TB during the year of my fieldwork and efforts were being made to address this. However, the issue of staff rotation was never fully resolved during the time I was there and, as far as I am aware, remains a problem.

## **(ii) Responsibility and Blame**

All of the nurses were well aware of the close relationship between TB and poverty. This was not only in relation to the mechanisms by which the disease is spread (e.g. overcrowded living conditions and poor sanitation) but also how it can be a barrier to attending the clinic for diagnosis and completing treatment (e.g. Farmer 2000; Compion 2008; Harper 2006; Harper 2010; Das & Das 2007). To give one notable example of this, I was speaking to the facility manager of De Doorns clinic, Sister Kotze:

JD: What would you describe as the major challenge at the moment, especially with TB?

R: You know, as soon as we diagnose, number one, it's poverty. Poverty plays a huge role in this community, and alcohol abuse as well. But as soon as the patients are diagnosed with TB, they start a few months or maybe a few weeks on TB treatment, but I think due to the poverty they need income [the implication being that they stop medication because of work].

However, with the daily frustrations of trying (often in vain) to steer several hundred patients through long and arduous treatment regimes, and the pressures placed on them from management, it is unsurprising that it was hard for them to always see the patients themselves as victims and to avoid placing blame upon their shoulders. Indeed, the discursive environment within which the nurses worked compelled it: the notion that patients must "take responsibility for their own health" was an almost omnipresent saying in the clinics, and invoked far more often by nurses than the corollary notion of patient rights. The fact that so many patients were not arriving at the clinics until they were at death's door and stopping their medication prematurely was usually enough to arrive at the conclusion that they were not honouring the responsibility to safeguard their own health.

The clinic nurses expressed this to me in a variety of ways, drawing upon the inherited language of patient responsibility to shed light on patient behaviour. Nurse Kriel of Empilisweni TB room, for instance, said: "At the end of the day the responsibility of your health is your own. You can't put the responsibility of being healed on someone else. You must stick to your appointments and the dates". Sister Pienaar, facility manager of Worcester CDC, expressed to me with great regret that it simply seemed that people in the Breede Valley did not care about health:

R: We do whatever we can, but at the end of the day it's your decision and your health, and you must come to the clinic.

JD: But that's the problem, isn't it, you've got on the one hand...one of the things that I've heard around, you want people to kind of take responsibility for their own health...

R: But they don't want to...It's very difficult for the staff because they are trying and they're doing their best, but at the end of the day if you are my patient, I can't just open your mouth and put tablets into your mouth. You know, it must come from yourself as well. And you know, the kind of community that we are serving, they are very...it seems as if they don't care. They really don't care.

What sticks out here is not only the way in which blame is placed on individuals, but perhaps more significant the way that generalisations were easily made. While it was the minority of patients that were visibly 'not taking responsibility', this was a stereotype which easily applied to everyone, resulting in an entire community being vilified as not caring: "they really don't care". Dr Van Zyl offered a slightly different reading of the situation. In his opinion, the reason that people are often not prepared to act in the best interests of their health is that "they do not have hope". In such an impoverished and disempowered community as Worcester, people's lives, in his opinion, often revolved around very immediate concerns, such making sure that they had food. A TB diagnosis, which entailed long-term commitment to taking unpleasant drugs – even when one is no longer feeling sick – was not, in his view, the primary concern for many.

Similarly struggling to make sense of the situation, Sister du Plessis' explanation featured a large overlap between the language of patient responsibility and Christianity, an association with a long history in South Africa because of the missionary origins of

biomedicine (Vaughan 1991; Marks 1994; Hardiman 2006; Hull 2009). This she drew upon in a fascinating way to explain why it was that people in Worcester often did not comply with the clinics' prescriptions:

If you look, the end of the world is near, and there are so many people whose heart is not right...Most of the people here, if you don't drink your pills, you haven't got responsibility. Because the Bible says that your body is the body of god, so you must look after your body. And illness is part of this, right? TB can be cured, you must only drink your pills and then you can be cured...If the patient can change his whole attitude, it changes his heart. He starts taking responsibility for his illness. He will take his pills and complete it. He will see that all the people in the house who cough, he will try and try and talk that they must come to give sputum and to test for TB. And to try and support them, if there's TB in the house, to drink his pills every day and to complete his treatment so that everybody at home can be cured from TB. All the children, younger than five, they will bring...give prophylaxis to prevent it. So, if the heart is right and it started at home, in each home, in each street...

In this passage, we get a sense that, for Sister du Plessis, the TB epidemic is not only a highly moral condition but also one that has risen to Biblical proportions. The reason for the magnitude of the disease is a wide-scale failing of people's "hearts" – "there are so many people whose heart is not right" – which worries her given that the end of the world and the Day of Judgement is near at hand. Vaughan (1991, p. 74) argues that "healing, for medical missionaries, was part of a programme of social and moral engineering though which Africa would be 'saved'". For Sister du Plessis, ridding Worcester of TB meant a combined emphasis on medical and moral healing, a sustained and community-wide endeavour to change people's hearts so that they attended the clinics. This, for her,

legitimised governmental intervention, the object of which was a particular imagining of immoral, irresponsible bodies that needed to be changed.

Yet reaching people with this message was precisely the problem. The clinics were disconnected from the communities that they serve, and those who most needed to attend the clinics seemed the least willing to go. Thus it was that Sister du Plessis composed the flyer with which this chapter opened, to be delivered to as many houses as possible via the home-based carers: “That is why the flyers must get out, right? The flyer must get to the home...The DOTS workers [home-based carers] who are in the field can go and give it out at the homes, you understand? Unfortunately for her, that flyer was never actually put to print. The managers deemed it too full of religious rhetoric and harmful language to be appropriate for mass distribution. One can certainly see why this was the case, given the kinds of words and phrases used: “disobedient patients who refuse treatment”, “evil” and “ghost town”. However, I would suggest that the reason that it was deemed inappropriate was the lack of sensitivity with which the message was composed rather than the message itself. Indeed, it was fostered by the discursive environment in which the TB nurses were working, compounded by their feeling of isolation. The flyer, I contend, ought to be read as an attempt – a desperate one, for sure – to get some kind of grip on what was happening “out there” and over which she and the other TB nurses seemed to have little or no control. On one level, Sister du Plessis’ efforts showed how much she cared.

### **(iii) Nostalgia for the Past**

The nurses drew heavily on the language of patient responsibility in order to explain the TB epidemic and attribute blame. However, the “gap between the clinic and the home”, as Dr Van Zyl put it, was so wide that it seemed often to outstrip the capacity of ‘responsibility-speak’ to offer tangible solutions to the problem. As a result, a number of

the nurses, especially those who had been practicing nursing during apartheid years, reflected back to a time when things seemed somewhat simpler. This is not to suggest that the nurses wished for a return to apartheid. It was just that certain forms of healthcare seemed to offer more effective means of controlling TB than the current prevailing paradigm revolving around the rights-bearing, responsible patient.

One aspect of healthcare during apartheid that was invoked repeatedly among the nurses was the active presence that nurses had in community settings. The assistant district manager Sister Kriel suggested the benefits of this community presence: “There was great interaction with your patients. It was nice because people who didn’t want to go to the clinic got seen”. Further to this, Sister Pienaar, facility manager of Worcester CDC, said that healthcare facilities had greater control over patients, who in turn listened to the nurses more: “we used to take the service to the community. We used to do home visits. There was more control over the patients, because the sister in the TB room can go out herself – that time the patients listened to us more”. Finally, Nurse Jacobs of Worcester CDC said to me: “Ja. You can ask Terence (another nurse). They’ve got a scooter and then they go out to call on the patients to come in. And they did come in, you understand, but now they don’t. They come once and never again...The problem is that they don’t care”. In the intervening time since the nurses stopped being such an active community presence, the home-based carers have, as we have seen, emerged to take on much of the work outside of the clinics. However, and despite being valued, there was a feeling that this was not the same as having trained nurses being able to go to people’s homes, not only because of the greater expertise of the nurses, but because people seemed to respect them more.

Part of the reason for this, however, was that patients had very few rights, and what seemed like respect was as much about subservience and obedience because of the fear

of the consequences. Sister du Plessis, however, felt that such was the scale of the TB epidemic that patients should not have the rights that they do now, especially in relation to TB control. In an angry moment, she said to me:

In the beginning, it [TB] wasn't such a big problem, but now it is, because of the defaulters. Now the patients have rights, but that time we didn't have rights like after 1994. You know, I think that is a big problem.

Few other nurses put the matter quite so matter-of-factly as Sister du Plessis. Nonetheless, patients being seen to 'abuse' their rights by failing to take responsibility was present in many nurses' narratives. Moreover, nostalgia for apartheid healthcare among nurses has been similarly observed by Walker and Gilson (2004, p. 1257). Again, as Walker and Gilson do, I would stress that the nurses in no ways expressed a desire to simply return to apartheid. Rather, these backward-looking perspectives just show how much of a disconnect there is between the theory of TB control and its reality on the ground. Therefore, it is perhaps unsurprising also that tried and tested methods that were acceptable in the old regime – for instance scolding, disciplining, even threatening to call the police – were invoked in instances where the prevailing logic of patient responsibility reached its limits. Whether these techniques are justifiable and what their effects are is another matter. Sister du Plessis, certainly, could cite many instances where patients had kicked and screamed their way through treatment but had later thanked her for being tough.

## **Conclusion**

In this chapter, I have attempted to highlight the challenges of TB control from the perspective of those working on the frontline of the epidemic. I have pointed towards a dissonance between the imaginings of how healthcare ought to function in post-apartheid

South Africa – rights-bearing individuals taking responsibility for their health – and the reality in which people were not attending the clinics once sick and ‘defaulting’ on treatment regimens. I have observed that the “gap between the clinic and the home”, as Dr van Zyl referred to it, is a product of a range of historical changes, including the restructuring of the health system, a lack of funding to support such changes and worsening socioeconomic and epidemiological conditions. And yet it was the nurses who shouldered the burden of negotiating this dissonance on the ground. By showing how they constructed TB as a moral condition which justified drastic measures, I have tried to show that the techniques deployed to get results were not deliberate attempts assert dominance over patients but rather ‘ugly’ acts of care in response to an ugly situation.

Yet, structures of dominance were exactly what was thereby reproduced through the interactions between the government clinic staff and their patients. Exasperated and overwhelmed, it was all-too-easy to lose sight of the structural determinants of TB that they knew to exist, to place blame upon individuals and, moreover, to generalise over the entirety of Worcester’s low-income, predominantly non-white population. Moreover, in Chapter 6, I will suggest that these discourses have been taken up and further moralised and reinforced by the community that is cast as such. TB control, I suggest, therefore constitutes a key site within part of a broader pattern of governmental discourse in healthcare and society more generally that, as Jensen (2008) observes, realises the very people, behaviour and groups that it seeks (explicitly at least) to transform. This is the context into which SATVI’s vaccine trials have been inserted, one experienced by the frontline clinic staff as hopeless and out of control. In the following chapter, through the eyes of SATVI’s team of fieldworkers, we begin our exploration of the institute’s vaccine trials by exploring what is happening in the very low-income settings that the clinics struggle so much to gain any control over. There we begin to see a series of social



processes moving in the opposite direction to the categorisations and interventions of the post-apartheid state.

## Chapter 5

### **“We Treat them as Special”: The Social Dynamics of Recruitment in Post-Apartheid Worcester**

Larry, a fourteen-year-old Xhosa boy who wanted to take part in the Adolescent Trial, squinted at a dusty photo on the table of a girl his age whom he did not recognise. We were in his mother's house; but Larry was no more familiar with it than I or the fieldworkers who I was accompanying. Larry had chased after the car while we were driving through Zwelethemba township, which was around five kilometres away from our current location, and when we stopped he had asked to take part in the vaccine trial. Fefe and Digby, the fieldworkers, had spoken to him before and knew that he had been living with his grandparents for the last ten years or so (although though they were not his biological grandparents but rather an old couple known to the family). Larry had been moved away from his parents' house when he was very young because of an abusive, drunken father and had not been in contact with either of his parents since then.

To take part in the trial, he could not provide consent himself; it was his legal guardians from whom consent had to be elicited, with Larry providing his assent (a separate form). We went to his grandparents to initiate this process. However, it transpired that the grandparents were not his biological relatives and did not have any paperwork to prove they were his guardians. This presented a dilemma: either give up, or do something drastic, namely to try to find his long-absent mother. Larry was, to my disbelief at the time, willing to activate the latter option, as were his grandparents. The mother apparently lived in Avian Park, a suburb of Worcester known for its gang-related activities. Knowing how much R150 could mean to a boy in Larry's position – the assumed, if unspoken reason for his interest – the fieldworkers decided to give it a shot. We drove over to Avian

Park and eventually found the house (after asking around), one of the most miserable shacks I had seen in Worcester to date, where we became part of a bizarre if warm reunion. Larry's mother was thrilled to see him. Embracing him, she asked him about life and school and paraded him around to meet her neighbours. Yet, this very quickly blurred into setting up the furniture for a group discussion – some plastic chairs around a broken table – followed by animated explanations by the fieldworkers about the all-too familiar threat of TB, the need for a new TB vaccine, clinical trials and rights of participants. Consent was eventually given, documents were exchanged, forms were meticulously signed and, at the end, Larry and his mother decided to meet again properly during the school holidays. During the drive back to Zwelethemba, Larry did not say so much as a word, clearly lost in a world of thought. Arrangements were made for screening at the trial site. All that remained of that encounter were a series of consent/assent forms, where Larry and his mother's names appeared side-by-side, mother and son, legitimising his participation in the trial.

SATVI prides itself on being able to fill its vaccine trials based almost solely on the basis of word or mouth or 'snowball sampling', at the heart of which lies its large team of field workers, a highly visible presence in Worcester who can be seen driving around in the institute's white, branded vehicles. This above vignette, while by no means an everyday occurrence, gives a sense of the social substance of recruitment on the ground and what goes on behind the scenes in order to produce the appearance of a smooth insertion of 'global' ethical practices into impoverished settings (cf. Sariola & Simpson 2011). Focusing upon SATVI's fieldworkers, this chapter builds upon an expanding body of literature on fieldworkers in African research settings. These have drawn attention to the important 'interface' roles played by these intermediary actors balancing the abstract, distanced requisites of formal research ethics with the situated, relational ethics of face-

to-face encounters (e.g. Geissler et al. 2008; Kingori 2013; Molyneux et al. 2013). The contribution of this chapter is, firstly, to shed light on the unique challenges thrown up by recruitment in a heterogeneous, stratified and often dangerous urban post-apartheid setting, and how the fieldworkers utilised their reputations, innovation and often bravery to complete their work. Secondly, it is to highlight a dimension of trial recruitment that is often overlooked given the emphasis placed upon material need: the value of participants to the research and the way that fieldworkers frame and vernacularise this message. I will demonstrate that the fieldworkers were acutely aware of the disempowerment and low self-esteem experienced by many of those with whom they interacted. They therefore believed that amongst the most important aspects of their work was conferring upon people a sense of being valuable, included and as capable of making moral decisions, something they were often not accustomed to elsewhere (as shown in Chapter 4). That this was considered so important by the fieldworkers problematises a tendency in existing literature on fieldworkers in African contexts to hold their relational work in opposition to the bioethical ideals of autonomy and altruism. The significance of this treatment for participants themselves will become clear in the following chapters, which introduces their perspectives into the frame.

### **Fieldwork in a Post-Apartheid Setting**

Fieldworkers, which go by a number of titles in different research contexts<sup>22</sup>, are research staff who are typically hired from the study communities in which research is conducted and whose work involves face-to-face, community-based interaction with participants. Often holding high school certificates and with previous experience in the NGO sector

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<sup>22</sup> E.g. data collectors, research assistants, community interviewers (Molyneux et al. 2013), or in SATVI's case, clinical research workers. I use the term 'fieldworker' because it is perhaps the most commonly used term in the literature.

(e.g. HIV counsellors), their roles include recruiting participants into trials (including conducting informed consent) and trial-related tasks for which medical training is not necessary, for instance collecting routine clinical data (Molyneux et al. 2010, 2013). Simon and Mosavel (2010, p. 4) observe that there are a number of pragmatic and ethical reasons for using fieldworkers to perform this kind of work: it contributes to local employment; the fieldworkers speak participants' first language; they have knowledge of people's norms and values and know local geography and community layouts; and they often have an "insider status" that fosters trust and communication between researchers and study communities (see also Molyneux et al. 2013).

Because of the income generated by formal employment, fieldworkers are often comparatively well off and with high social standing in the communities in which they work. At the same time, they tend to be amongst the lowest in the institutional hierarchies of research institutes because their role, unlike medical and scientific staff, requires few qualifications. While their work is easily construed as 'simple', ethnographic studies have shown that they play a vital and under-recognised role mediating between the abstract, distanced world of 'global' science and ethics and the material realities in which they land (e.g. Molyneux & Geissler 2008; Molyneux et al. 2013; Kingori 2013). In one of the most influential studies of clinical trial fieldwork, Geissler and colleagues (2008) show that the success of a malaria vaccine trial in The Gambia hinged at least partially on the ability of fieldworkers to counter the perception that the trials represented European interests by couching trial relationships within a familiar idiom of kinship. "He is now like a brother, now I can even give him some blood", as one participant explained (see also Gikonyo et al. 2008; Leach & Fairhead 2011). Focusing more specifically on consent encounters, Kingori (2013) demonstrates that for data collectors in western Kenya, the principle of autonomy was peripheral to the data collectors' ethical practice, who instead acted upon

their own interpretations of justice and beneficence. Also in Kenya, a recent collection of papers (Molyneux et al. 2013) comprehensively describes and analyses the variety of roles that intermediary actors play in clinical trials and the ethical challenges that the use of these actors pose. Taken together, the literature shows that “relational ethics” – that is, the ethics of face-to-face encounters – is crucial to the success of clinical science in contexts of extreme inequality (Geissler et al. 2008; Molyneux et al. 2013), a necessary corollary to the abstract tenets of formal research ethics.

SATVI’s fieldworkers are like those in other African research contexts in many respects. First-language Afrikaans or Xhosa speakers, the fieldworkers are hired from the Breede Valley and have an excellent knowledge of the geography of the area, values and norms and are well known and trusted. The following section gives a sense of their backgrounds, social standing and how this informs the trust and reputations they have in Worcester. Yet, as Simon and Mosawel (2010) argue, fieldwork and its associated challenges can vary greatly depending upon the nature of research and the degree of immersion of fieldworkers in trial communities (see also Molyneux et al. 2010). Several of the aforementioned ethnographic studies took place in rural settings where fieldworkers lived amongst participants throughout the duration of studies and often became deeply embedded in people’s social networks (if they weren’t already). The challenges that the fieldworkers faced and how they tried to overcome them were influenced by this high degree of immersion (Molyneux et al. 2010). While the fieldworkers often knew, or developed, relationships with participants, Worcester’s heterogeneous, stratified, destabilised and often highly dangerous urban environment threw up a unique array of challenges which departs from other accounts. In one day, I will demonstrate, they could encounter affluence, destitute poverty, people from different cultural backgrounds to themselves, and gang violence.

Perhaps unsurprisingly, then, when spending time with the fieldworkers I began to appreciate a slightly different skill-set that they were drawing upon to complete their day-to-day work. This was, certainly, a form of relational knowledge. However, it was often not so much of an ability to maintain prolonged relationships, but rather adopting a state of continual adaptability, flexibility and responsiveness: a tactile knowledge of people, norms and values and also of geography, materials, domestic spaces and social networks. The necessity for adaptability was heightened by the fact that in different moments the fieldworkers were dealing with very different imperatives. When attempting to generate productive ‘snowballs’, they were often implicitly relying upon the poverty and abjection that made people available objects of experimentation. By contrast, in the consent encounters themselves, another series of concerns came to the fore. Trust had to be established, suitable consent environments constructed, documents assembled, narratives rehearsed and, perhaps most significantly, attempts made to ‘lower’ oneself to uphold the dignity of people in impoverished living circumstances. The main point that I want convey is that the fieldworkers were concerned with making the consent process meaningful to people: getting them interested in the science and what their role in it was; to put them in a position where they were making a genuine moral choice (cf. Kingori 2015); but most pertinently to make them feel valued and worthy, not only as participants but more generally as people. This chapter thus begins to chart the transition that people undergo from being *abjects* to *objects* to *subjects* (Sariola & Simpson 2013), which I introduced in Chapter 1 to help draw out the meaning and significance of SATVI’s trials in people’s lives.

### **Fieldworkers and Community Life**

Speaking to the fieldworkers, both on the road and during interviews, most described themselves as outgoing and extraverted but also trustworthy and discreet people who had

a passion for working with and for the community. In SATVI's formative years, as we saw in Chapter 2, the fieldworkers were HIV counsellors who had been contracted from the Treatment Action Campaign (TAC), and had therefore developed skills and reputations through their work in this capacity. Since then, the fieldworkers have come from a variety of backgrounds, and even those from a counselling background staked their reputations on a wide variety of roles which combined and fed into their work for SATVI.

Speaking to Edna, who had worked for SATVI since the BCG trial, she explained that she was not only known for her history as a counsellor, but as being active in the church, as regularly attending community events and funerals, and even brokering reduced taxi costs from R10 to R8 as price rose beyond what people could reasonably afford. Alex, an optometry technician by training, seemed to know every other person in Worcester, making sure to acknowledge everybody he knew as he drove through the town. He was also known and respected among the younger men because of his involvement in motorsports. Nomvula, another previous HIV counsellor, was very well known and respected in Zwelethemba because her mother ran a soup kitchen, which she had taken over. She had recently also taken to selling meats. Other backgrounds of the fieldworkers included KFC manager, hospital clerk, nurse and home-based carer.

It was noteworthy, however, that while they considered themselves to be respected individuals with good reputations and the trust of those they worked with, most were considerably less comfortable and self-assured in the more affluent and predominantly 'white' suburbs. This again testified to the stratified nature of post-apartheid Worcester and the way the town remained divided by Durban Street. There were, however, one or two exceptions among the fieldworkers, for instance Demi, who was regarded as having an air of "high class" and "respectability" (*ordentlikheid*).



Coming from a middle-class background, she had found it difficult initially to adapt to conducting recruitment in “dirty” places and, while she was used to it and even enjoyed it on occasions, remained more comfortable recruiting in wealthier areas. This suited the other fieldworkers just fine, and they were happy, for instance, to let her conduct any work in the affluent suburbs. Nonetheless, as I will show below, working in these areas was likely to be far less productive than in the dense, accessible social networks in lower-income suburbs.

### **The Closures of Affluence**

Spending time with the fieldworkers, I began to get a sense of what was viewed as a ‘successful’ day in the field. Three completed informed consent forms per day was par for the course. Four, five or more was be considered a productive day. Two, one or nothing – a far more common occurrence than the fieldworkers would have liked – was usually viewed as unsatisfactory. The recruitment cycle typically began by searching for people who had already given their details to SATVI, for instance by phoning the site or, in the case of the Adolescent Trial, putting their names and details in the box at school. From there, the hope was that further interest could be generated via people’s contacts and networks. However, this tended to be far easier in the lower-income parts of town.

On one afternoon with Demi, we had a more ‘successful’ afternoon than expected precisely because it took an unexpected turn. We were out looking for a ‘white’ young man who had put his name in the box at Drosdy High, one of the middle-income schools of Worcester. However, we were having difficulty finding him because he had left two addresses, one his dad’s home in a block of flats in central Worcester, the other his boarding house at school. The problem was that, at his dad’s house, nobody was answering the buzzer, the phone went straight to voicemail and there was also nobody around, such as a neighbour, to ask whether they were in. We were eventually forced to

give up, and so we drove to a nearby shop and Demi got out to get something to drink. But in addition to a drink, Demi returned with two ‘coloured’ Afrikaans teenagers, who got in the back of the car. Demi exclaimed, “well these two are interested at least!” – they had recognised the car and approached Demi in the shop. We drove across Durban Street and down to Esselen Park, where the young men lived next door to one another. While I reserve a detailed discussion of how the consent process itself was conducted until later, both sets of parents fully supported the boys’ participation in the trial and, within about half an hour, Demi had two completed sets of consent and assent forms signed and an appointment made for them to come to the trial site for screening.

Demi was already fairly satisfied, given how the afternoon had started. However, on the way back to the car another of the boys’ friends walked up and, recognising what had happened, asked to participate too. It turned out that he lived in a more dangerous area near Riverview. Demi, realising that this would take her out of her comfort zone, asked the teenagers (who had already been recruited) to join us for safety reasons. After the short drive, on the way into the boy’s house we walked past rows of men drinking, and Demi, despite her fear, smiled warmly at them as we walked past repeating “*goeienaand* [good evening]”. After finding the boy’s mother in the kitchen, Demi decided that this was not an appropriate environment for conducting the consent process, and so she took the boy and the mother back to the car, where she conducted the whole process in the dim overheated car light, leaning over into the back seat from the driver’s position, while the two teenagers stood outside guarding the car. After the final signatures were in place, we drove the teenagers back home and headed straight back to the office with a sigh of relief.

This series of events says much about the social substance of snowball sampling and where it does and does not work. The reasons why it was difficult to recruit

participants in wealthier suburbs were multiple. Firstly, the fieldworkers generally had fewer contacts in the affluent areas of Worcester, making it difficult to find a point of entry into their social networks. But even in the Adolescent Trial, where the fieldworkers had the details of interested parties in advance, in the frequent event that phones were not being answered, it was tricky to actually get face-to-face with prospective participants. Most simply, this was because there were usually high gates and walls around the houses, and as often as not the buzzers had been removed from the sockets. The removed buzzers in particular signalled a disdain for uninvited people – a measure which, while usually taken to deter ‘hawkers’ or job-seekers, was also off-putting for the fieldworkers. Secondly, even if initial interest had been expressed, the fieldworkers were pessimistic about their chances of successful recruitment. The feeling was that parents would often want nothing to do with TB and would refuse to let their children participate in the studies before the fieldworkers had even presented any information. Nomvula, for example, expressed how this had transpired in her experiences:

I go to everyone, except the ones that I know are going to say no. But the people that are at my level. When I say people at my level, the lower level...it’s good for me because it’s easy to talk to them. Those ones with the big houses who are fancy, I really don’t go to those houses because the parents are going to ask, “why is she here? We don’t want those girls to stop at our houses”.

Nomvula was referring to wealthy people in general. However, I was speaking to Peter, a lively and confident Afrikaans fieldworker, who felt that it was ‘white’ people in particular who were less likely to let him into their homes. In fact, for Peter the pursuit of ‘white’ participants for him was doomed from the start:

I can't think like white people, really I can't. Because coloured and black people if you start talking to them they invite you into their houses, and say "no sit man sit", and then they talk...But if I go to white people, neh! I never got the white people...Not that I'm afraid of going there, or don't like them. I just know for sure that no, I won't get that person to be a participant, so I'll give it to them who are more comfortable [e.g. Demi].

Whether it was 'white' people or more affluent people more generally, what the concerns of these fieldworkers had in common was that the refusal to take part was not based upon a consideration of trial-related information (e.g. risks and benefits). Rather, the decision not to take part had been made before the fieldworkers could even begin.

Although rates of TB were much lower in affluent areas, it was interesting to find that, from the perspective of the fieldworkers, the primary reason for nonparticipation was not a lack of experience with the disease or even that the risks outweighed the benefits. Instead, for them it was because of the association of the disease with 'poor', 'dirty' and 'coloured' bodies, which was discussed in the previous chapter (see Abney 2011). That TB stigma was the driving force behind refusals was hinted at by Nomvula's expression: "Why is she here? We don't want those girls to stop at our homes". But it was stated more explicitly by other fieldworkers: "you know when it's a nice house they don't want to participate, because of the stigma" (Judith); and: "They think it's something dirty...If you have TB, everything is dirty....so they don't want to be near you" (Demi). Now one might well ask, why was stigma an issue when it was healthy individuals that SATVI were interested in recruiting into its trials? It seems that many people just heard "TB" and, regardless of the finer details, immediately wanted nothing to do with the research and stereotyped those recruiting for it. Indeed, from the accounts of some of the fieldworkers, it seemed that people often reacted to them as though TB itself had come

knocking.

### **Avalanche Sampling and Gang Territories**

By contrast, recruitment in the lower-income suburbs was, as suggested by my experiences with Demi, considerably more productive. Firstly, the task of approaching people and households in these areas was already facilitated by a high degree of familiarity with SATVI's work. The white branded vehicles were such an active presence south of Durban Street that, every time I was out with one team of fieldworkers, it was rare not to bump into another team or two along the way. Moreover, calls of "the TB people" often followed the passing of the vehicles, and the fieldworkers waved or hooted at those (great many) people who they knew personally and/or as participants in the trials. This made the task of setting in motion productive 'snowballs' considerably easier.

A snowball could commence with the name of a person who had responded to an advert or dropped their name in the box at school. In those instances, the index case could usually be relied upon to give the fieldworker at least one name. But this was often not even necessary. For example, recruitment activity for one trial could start where the last left off: by approaching a household which already had an established history of participation. In fact, often the fieldworkers did not have to go in search of participants; interested parties would come to them. Several fieldworkers expressed this to me. Ruby, an Afrikaans fieldworker from Riverview, said to me in the car one day that "all the people in Riverview know me and they will find out what study I am on and want to take part in that one". Edna, moreover, said that: "when I come home from work and the car stops there, then there's a couple at my house waiting for me: my child is this and this. Then I say, yes, it's fine, I do have the stuff [consent forms] at my home". Alex even said to me that there was one teenager in his street who, of his own volition, produced a list of interested people for him:

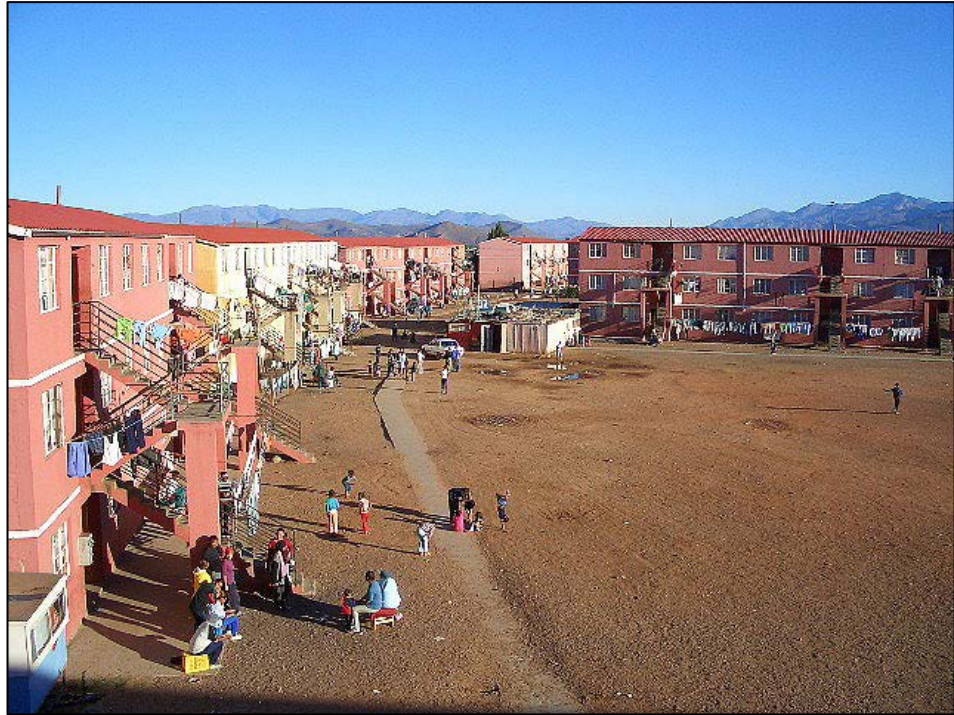
There's one kid who I don't even know personally who come up to me and says "uncle [Alex] I've got some names for you". And he'll have like eight to nine names and addresses! So, that's the reputation I have built. This kid's a participant, and he must have seen me spinning [a motor sport] or something. All of a sudden people know who you are and associate you with SATVI.

With considerable pressure to enrol as many participants as they could, it is little wonder that the fieldworkers devoted more of their time and energy to recruiting in Worcester's low-income suburbs. Indeed, what they were engaged in can probably be more accurately described as 'avalanche sampling' than 'snowball sampling'.

While this gives the impression that recruitment is simple in these settings, it is important to recognise that most of Worcester's poorest suburbs were coextensive with gang territories. The main gang territories were located in Roodewal, Riverview and Avian Park, and within the former two, the areas where the gangs were most active were the blocks of flats (Figures 11 and 12). The way in which these flats were constructed is consistent with the apartheid regime's "racialized modernist vision" (Muller 2004, p. 56), low rise and uniform. While these flats were viewed by the predominantly 'coloured' as safe and friendly during the 1980s and 1990s, in recent years they have been colonised by gangs and the way the blocks are bounded and with large public spaces in the middle of them make them easily demarcated territories. When driving into Roodewal flats, one can see children sitting on the road, who are paid by the gangs to keep an eye on who is entering and phone them if police, rival gangs or anyone not welcome passed by.

At the time of my fieldwork, people were injured or killed on a daily basis – and the victims were not always gangsters. It is perhaps no surprise that, as we saw in the previous chapter, these were precisely the areas that the government clinics found so hard to access and gain any control over (even though Worcester Community Day Centre was

only a few kilometres from Roodewal flats). SATVI's management were well aware that their staff were working in these areas and took measures to ensure that they were as safe as possible: the fieldworkers always travelled using cars; they were to go out in twos; and they were not to recruit after dark when things got 'lively'. Yet as fieldworker Maggie said of recruitment in gang territories, "you never really know what's going to happen".



**Figure 11: Roodewal Flats**



**Figure 12: Two separate teams of fieldworkers coincidentally arrive at the same block of flats in Riverview**



With the dangers of gang violence ever present, the fieldworkers relied heavily on their personal reputations as community workers and being known by the gangsters themselves. In fact, not only did the fieldworkers say to me that they have the licence to move around unchallenged but, moreover, would often be offered protection and warnings about gang fights so that they did not get caught in the crossfire. Christine, for instance, related an example where her colleague was challenged by some gangsters because she was not known to them personally but, upon finding that she was working with Christine, was offered protection while they worked:

We were there, earlier this day, I parked the car and this guy came and asked [Imogen], “with whom are you working here?” And she said “with [Christine]”, and he said “ok ok ok we will stand here by the car and watch the car... So, people is knowing us. And especially when there’s gang fights, they know we are busy recruiting at the flats, then the ‘small’ gangsters will tell you, you must now get done because the gangsters – the ‘big’ ones – is coming. Or there will be a shooting, or a robbery, or this and that...so you must just go. You can come tomorrow again. Or you can come and just ask them, can I come? And they will say “no no not today, it’s not safe”.

Here we can see how heavily reliant SATVI were on the reputations of the fieldworkers in order to access the people who were living within the scope the informal control of the gangs, particularly the way that they were seen to be looking out for the interests of people in these impoverished settings.

With that said, such was the pressure to generate sufficient numbers of participants that the fieldworkers sometimes pushed their luck. Mira recounted a recent experience where she was in one of the Riverview flats conducting the informed consent process with a prospective participant. The backdrop of the consent process, however, was Ruby

sitting downstairs in the car with the engine running whilst a gang fight moved nearer and nearer to the car. Mira said that she left it until the last minute to get the final signatures in place before hurrying to the car and both of them driving to safety. None of the fieldworkers were entirely comfortable with working in gang territories and, moreover, there have been much closer calls that it would be inappropriate to mention here. However, the way that this was generally expressed was that it was just ‘part of the job’.

### **‘Reimbursements’ and the Unemployed**

Before moving on to an exploration of the consent process, it is important to state explicitly what, from the fieldworkers’ perspectives, was causing word of SATVI’s trials to spread faster than TB itself through Worcester’s low-income suburbs. Most suspected that, at least at the point of recruitment, it was the R150 ‘reimbursements’<sup>23</sup> that were greasing the wheels of the recruitment bandwagon (I will show shortly that during the consent process they attempted to counter this imagining). One can certainly see why: mention of R150 seemed to follow the fieldworkers around wherever they went, although almost exclusively among young men, who often made ‘blood-for-money’ gestures at the cars. This involved rubbing one’s thumb and fingers together (indicating money) and pointing an index finger to the inside of the other arm (indicating blood draws). One young man, for example, came up to the car window while I was with Peter and said, “my blood is veeeeery expensive, you must give me R300”. Below and especially in the following chapter, we will see that this was precisely the image that threatened the respectability of trial participation and that people tried to consciously distance themselves from (Jensen 2008).

There has been extensive bioethical debate as to what amount of money – if any –

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<sup>23</sup> R150 was worth approximately £9 at the time of writing.

is ethically appropriate to give to clinical trial participants. Positions range from the conservative bioethical one that any situation in which participants can receive a net gain is ‘undue inducement’, to the view that participation should be reconfigured as ‘clinical labour’ in which determining a fair wage is the primary ethical priority (Geissler 2011; Sachs 2011; Cooper & Waldby 2014). In line with the former position, the R150 given at each scheduled study visit was conceived strictly as ‘reimbursement’ for losses, not an incentive and certainly not payment. However, the fieldworkers thought that the regular receipt of R150 was more than a ‘reimbursement’ and rather a significant contribution to household income. Several believed that SATVI’s trials would not generate interest without it. Harry, for example, said to me:

But you know I think people do it more for the money. That is how I see it, because the kids will tell me “my mum’s waiting for this money I need to buy this and that”. If we didn’t have that incentive, we wouldn’t have any participants.

Moreover, some suggested that one of the reasons that SATVI enjoyed privileged access to the gang territories, in addition to personal reputations, was that the institute was putting food on gangsters’ tables. Lincoln, one of the drivers, expressed this:

The other thing is it’s also helpful for the community, in that the 150 is important, and in some areas, it helps us to get into that area, especially where the gangsters is. They know that maybe one of their family members is a participant so maybe in the morning there is no bread, but after we bring them home they know there’s money that can be used. That also covers us to go into areas.

We might therefore suggest that when SATVI was known for community work, this was

not only for its research but also for the ways in which the institute had become part of and perhaps even helped to sustain the shadow economy of gang life.

On a more general level, several of the fieldworkers said that the whole recruitment business was implicitly reliant upon Worcester's high unemployment rates. The simplest evidence for this was that most recruitment activity for the adult trials took place during what would usually be working hours, and therefore those who were available to them – and amongst whom productive 'snowballs' of participants were likely to occur – were disproportionately those not working. One fieldworker, Anette, even hinted that she included unemployment as part of the 'inclusion criteria':

If I go out in the field, I'm looking for specific age groups, say 18-50, then I know this person was part of my previous study. Then I will ask them, "is there still some people in your family who are not working and is between the ages of 18 and 50?". Then they will say, "no not in my family, but in that family and that family".

The reason for seeking the unemployed was not only in order to generate interest, it might be noted. It was also in the interests of retaining participants. I was informed that even though site visits can be arranged so that it does not interfere with people's work, those who found employment often dropped out of the trials. This, in a sense, made unemployed people 'better' participants, ones who will see the trials through. I do not wish at this point to take any position on the matter, because below and in subsequent chapters we will see how resistant many people were to the suggestion that participation is or ought to be just about material gain. Nonetheless, from the fieldworkers' viewpoints, the 'reimbursements' were a significant lubricant for the spread of interest in the vaccine trials and that, ultimately, a high percentage of SATVI's participants were unemployed.

## **Spaces and Relations of Consent**

So far, this chapter has focused upon how the fieldworkers handled the pressure to generate a sufficient quantity of participants to fill SATVI's trials and how they navigated Worcester's stratified urban environment. Yet, they also had to conduct high *quality*, GCP-consistent consent processes. The imperative underlying informed consent is the provision of clear, accurate information about the research and the voluntariness of participation such that informed, autonomous choices can be made (Geissler et al. 2008; Gikonyo et al. 2008; Geissler 2013). There is also, as will be discussed in the next section, a bureaucratic element, involving the meticulous filling of forms and gathering of proper documentation. The challenge was that, as recruitment activity was channelled into Worcester's poorest areas, the social and material environments in which people lived did not easily translate into the world imagined by GCP, often living in destitute poverty, with high unemployment and few opportunities, and fragmented familial and social relationships.

Given the dissonance between bioethical ideal and material reality, a considerable amount of work was often needed before the process of eliciting informed consent could even begin. In the opening vignette, we saw Digby and Fefe having to contend with the fact that Worcester was not a setting in which one can safely assume that adolescents live with their legal guardians. But ultimately this did not deter them. Given Larry's wishes, they devoted an afternoon (at the expense of recruiting larger numbers of participants, it might be added) to bringing him and his mother together so that their names could appear side-by-side on the consent/assent forms. One effect, it might be noted was that the consent process went some way towards creating the reality it purported to represent:

Larry and his mother re-established their relationship.<sup>24</sup> During my time with the fieldworkers, I heard several stories where they travelled extensively, sometimes to far-out farms, to track down the mothers of adolescents so they could take part.

Aside from assembling the necessary individuals, other conditions also had to be met before the consent process could proceed. Upon entering the house of Larry's mother, a mattress had to be dragged out of the way into a corner, what limited furniture was carefully arranged, and Larry's mother especially went out of her way to ensure a 'proper' environment for the interaction – cleaning, apologising for the mess, and fussing while the fieldworkers tried to assure her that she needn't worry. In the scene with Demi, too, she realised that a house full of drinking men was not an appropriate environment for performing informed consent, and so she used the car instead. This was by no means a perfect setting, either, especially regarding the complex exercise in form-filling (discussed next section). However, it is perhaps worth reflecting how valuable the car was in this regard: not only was it a means of getting around in an often-dangerous setting, but it also provided a safe environment for the consent process. Ad hoc decisions like this were frequently made in the course of recruitment and often crucial for its success.

One of the things I was attentive to was the ways in which the fieldworkers conducted themselves when entering the homes of Worcester's poorest – how they established trust, made people feel comfortable and created an environment within which the consent process could take place. Ethnographic studies of fieldworkers have highlighted a variety of ways in which social relations of consent are established, including being known as part of the community or otherwise as 'good' people (Kamuya,

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<sup>24</sup> When interviewing Larry at the site a few months later, I found that their commitment to see one another again had been followed up on and they were still in contact. Moreover, while I do not quote Larry directly in the following chapters, like many other participants his reason for wanting to take part was not for the money, which is what the fieldworkers assumed. Rather, it was because he wanted to find out more about TB and about whether he was healthy.

Theobald, et al. 2013; Kingori 2013), carefully balancing allegiances (Chantler et al. 2013; Molyneux et al. 2013) and using familiar idioms to counter suspicions about the foreign interests of the research (Geissler et al. 2008). Speaking to SATVI's fieldworkers, perhaps the most important aspect of the dynamic between themselves and prospective participants that they felt they had to address was their positioning as comparatively well-off individuals representing a powerful organisation, which ran the risk of coming across as superior. Consequently, they unanimously thought that the most important attribute of being a fieldworker is the ability to 'lower' oneself and, moreover, to be mindful of the ways in which people arranged their domestic spaces, for example how they designated public from private (not easy within a few square feet). Alex expressed that this was hard-learned but incredibly important:

What I've learned in this whole SATVI thing as a CRW [fieldworker] is that you have to be level with the ground... You can't go there sitting in people's places with a type of attitude that you are a 'highly tighty' and that people are living in the squatter camps. The conditions are not so great. So you have to be really 'to the floor' [gesturing downwards]. I remember my starting years and I had to go into the camps, and it would be a one-room place. But you can't go and sit on their bed because that's their privacy, you have to adapt to certain kinds of things. So you say "I'm going to make myself comfortable". And they'll say sorry and make excuses but you say "no you don't have to make excuses".

Nomvula, similarly, said that it was important to not to make it seem that they were a means to an end, which meant talking and presenting oneself to others in the "right way" and not in a way that made one seem "high class":

The main thing is that you must talk to the people in the right way. Not like you just want to finish this work. So I'm always smiling and I always laugh. And then I don't have styles. If I go to the small *hokkie* [small shack, literally chicken coop], the people say, "no, just sit here." I say, "no, don't mind, I'll sit here on the crate". So, you must make as if you become like those people. Don't go to their houses and say "oh I'm smelling this, I'm high class".

It might be noted that this practice departs in certain respects from Kingori's (2013) experiences with data collectors in western Kenya. Using illustrations composed by the data collectors, she shows that they saw the consent process as taking place across a large material divide between themselves (as representatives of power) and the people with whom they interacted. Material difference, rather than the bioethical ideals of autonomy and altruism presupposed by the notion of informed consent, was the dynamic characterising the encounter. By contrast the fieldworkers, perhaps with more in common with the fieldworkers observed by Geissler and colleagues (2008) in The Gambia, sought to mitigate against this gap and reconcile the respective interests of SATVI and the community they were concurrently a part of.

The way in which the fieldworkers lowered themselves was, in a sense, consistent with the bioethical imagining of the researcher-subject relationship. For in lowering themselves, their interlocutor was simultaneously in the ascendant, which inverted, however fragilely and temporarily, the power relationship between them. However, the motives of the fieldworkers and those of the ethical practice that they were charged with carrying out differed in at least one important respect. Whereas informed consent seeks to render visible the autonomous, rational, continuous person that can appear 'on paper' (Simpson forthcoming), the fieldworkers were far more concerned about the situated, relational individual in front of them and how they might make them feel valued, included



and moral, not only as participants but more generally as people. Fiona Ross, commenting on her informants' attempts to build meaningful, respectable lives, writes: "Desperately afraid of being considered *weggooi mense* (throw-away people; it has connotations of being discardable, reject, surplus), they worked hard against the prevailing stereotype, to reframe themselves as valuable" (F. Ross 2010, p. 8). The ways in which the fieldworkers engaged with Worcester's poorest reflected their awareness of what participation might mean in this context. Peter, for instance, described how he expressed to people their importance to SATVI:

The name of SATVI as the institution must be known, I'm working for those people and they appreciate what *you*, as a participant, are bringing to them [his emphasis]. We are glad you have blood that is part of the study. Because not only SATVI, but the whole of your country needs you. Then you will see there's a change. They really appreciate being valued...In healthcare, the patient needs the hospital. Here I exchange it and say SATVI needs you.

Magda, while talking about home visits post-enrolment rather than trial recruitment, made more explicit reference to how downtrodden people often felt and how their work could make a difference to that:

Those few minutes that you connect with people and before you said goodbye, you can do something great in that person's life, with a few words, to make them feel worthy, to make them feel special. Because we work in areas that people have very low self-esteem...Without giving them a cold shoulder, you can use that minute or two to make them feel a little bit better, and to take on the day, and the next day. CRW [fieldworker] is a very important job.

Mira, similarly, stressed that they treat people as "special" and, similar to Peter above,

observed also that this relationship differed from the way in which they were treated in the government clinics:

Maybe it's the way of approaching them. We treat them as special. As people equal to me. Not like you're below me. That's many times, even if the nurses don't that way [in the clinics], that's the impression that the patients got. But in the community, we as SATVI are like, "Hi tannie [auntie], how are you doing?" And you know you come to their level.

This aspect of what trial participation means in impoverished settings is, I think, not highlighted enough in the literature. A common focus of anthropological critique has been how the abstract tenets of research ethics, especially autonomy and expectations of altruistic intent, *miss* the realities of research on the ground. Yet as I argued in Chapter 1, the way that this critique is advanced by drawing attention to the material benefits of participation arguably reinforces an image of 'vulnerability' that reduces the possible significance of medical research in people's lives to its material dimensions (Chambers 1989; Levine et al. 2004). Yet my findings with SATVI's fieldworkers raise an alternative concern. Well aware of the treatment and stereotyping that people were subjected to in their interactions with the state and its employees (see Chapter 4), the fieldworkers saw their roles as important because of the ways in which they were able to move back against the inscriptions of the state on people's lives. In this regard, the bioethical ideals of autonomy and altruism did not simply miss the reality of research on the ground. To the contrary, the fieldworkers saw the profound effects that treating people as valuable, worthy individuals capable of making moral decisions could have in an environment that threatened to erode the possibilities for positive self-imaginings. The following two chapters add to this emerging picture the perspectives of trial participants themselves.

## Filling in the Forms

The verbal component of consent was an important part of the work that the CRWs had to accomplish. However, a number of anthropologists have observed that, when push comes to shove, it is meticulous documentation that matters most in research governance (e.g. Petryna 2009; Douglas-Jones 2012; Simpson et al. 2015). Testimony to this was just how much paperwork needed to be filled in and documents to be assembled to legitimise participation. People's birth certificates and clinic cards needed to be produced. Proof of parenthood or guardianship for the adolescent trials. Most importantly, *three* copies of the long and drawn-out consent forms had to be completed (one for SATVI and the regulators, the other for the participants), each of which required multiple initials and signatures. So intimidating were these forms that the fieldworkers often hid them from view until the last possible moment. In this final section, I will suggest that the bureaucratic component of consent had the potential to undermine the trust that the fieldworkers had developed with participants, requiring yet more compensatory work in turn.

The challenge, as with the verbal component of the consent, was that in an impoverished setting, it was not easy to make the world appear 'on paper' as the regulators demanded it. It was, in fact, an utter nightmare. One problem was that many of the adults in Worcester and some of the adolescents struggled with writing, and therefore the seemingly simple task of writing their names out in full multiple times in block capitals before signing them was very challenging. This was compounded by the fact that people's names had to be written precisely as they appeared on the birth certificates, which was often different from the way that people spelled them in everyday usage. GCP dictated that any mistake, no matter how small, had to be crossed out with a single straight line (such that the mistake was legible), as well as dated and initialled by

the participant/parent, before the correction could be written. This could, naturally, result in a downward spiral: mistakes on mistakes on mistakes.

Kingori (2013, p. 365) observed of fieldworkers during a trial in Kenya that too much attention given to the consent forms “often increased suspicion and undermined trust in the verbal assurances given about the benefits and safety of their participation”. From my experiences with the fieldworkers, I would add that one sure way of undermining the fieldworkers’ efforts to make people feel valuable and worthy was to lay bare people’s compromised ability to write to the point of humiliation. For example, I was with Demi in one small house in Riverview while she conducted the consent process with a mother and her son. The mother had been completely happy until this point. However, making mistake after mistake, correction after correction, she was getting considerably distressed with the process and, in between each of the multiple forms, wondered around the kitchen muttering under her breath, “*baie skryf* (much writing)”.

The resourceful individuals that they were, the fieldworkers did however devise multiple techniques for minimising the negative effects of the form-filling. Demi, for instance, had realised that something so simple as offering people her pair of reading glasses could make a world of difference, something that people might not mention otherwise. More common techniques included, firstly, giving people a thorough pep talk about the need for accuracy but equally, that the process would take as long as needed – so ‘don’t worry’. Secondly, they placed the relevant birth certificate directly above the space on the forms where they would write, thus minimising the chances of mistakes. Thirdly, in cases where people were clearly uncomfortable with writing, the fieldworkers often stood close by, orchestrating almost every letter as it was composed. Of course, this ran the risk of coming across as patronising, even reinstating the power imbalance that they had tried so hard to counteract. Thus, anything like this was performed with great

caution and without looming over them. Finally, given that two copies of each form were needed, the final act was to fine-comb through the forms and decide which looked neater, with the scruffier of the two invariably given to the participants to keep.

It is with these considerations in mind that one can see why the fieldworkers tended to conceive of GCP not simply as a guideline for action but also the action itself; the verb ‘to GCP it’ was used to capture the act of squeezing the consent encounter into the meticulous documented format required to legitimise participation. In short, the process of filling the forms was the final hurdle but one of the most difficult. It was, by a distance, the aspect of consent that the fieldworkers enjoyed the least, but it was one that had to be taken at least as seriously as the others. The last thing that was wanted was to have to return to the same house the following day, with a fresh stack of paper, to see the distraught look of a participant whose previous evening was already spent filling in forms.

## **Conclusion**

This chapter focused upon the work SATVI’s fieldworkers, a highly-skilled group of individuals who mediate between the institute and the community on whom its TB vaccine trials are conducted. Their recruitment practices, I have shown, were concentrated upon precisely the low-income suburbs of Worcester – Roodewal, Riverview, Avian Park and Zwelethemba – that the government clinics struggle so much to assert influence upon (Chapter 4; see also map – Figure 2 – in Chapter 2, p. 50). This is partially because it is in impoverished setting that TB finds greatest traction (Farmer 2000; Benatar & Upshur 2010). But it is also because, in contrast to the more affluent suburbs north of Durban Street, it is in these areas that the fieldworkers were known, respected and trusted and where social networks were more dense and accessible.

By exploring the social dynamics of recruitment practices in a heterogeneous, stratified and often dangerous urban setting, this chapter builds upon the expanding

literature on fieldworkers in African research contexts. While fieldworkers are generally hired to perform ‘simple’ tasks for which medical training is not required, ethnographic studies have shown that they play a vital, ethically-charged mediatory role balancing the objectifying logic of trial protocols and the needs and expectations of study populations (e.g. Molyneux & Geissler 2008; Molyneux et al. 2013). As I have shown, SATVI’s fieldworkers needed to draw upon a wide variety of skills as well as personal reputations in order to meet the dual and often competing demands of both their employers and residents. This included engaging the wealthy, generating productive ‘snowballs’, navigating gang territories and conducting a consent process that was in many ways blind to the challenges that they faced when entering the homes of Worcester’s poor.

I have also highlighted a dimension of clinical trial recruitment that has not received much attention in the literature: the ways in which the fieldworkers conveyed to people their value to the scientific endeavour and how they made it relevant to the setting in which they were working. The consent process is the point at which people living in conditions of abjection are entered into the ‘global’ scientific and ethical structures of clinical trials. On one level, the moment of enrolment is when trial protocols begin the process of rendering people into standardised, commensurable *objects* of experimentation. But at the same time, they also become visible as particular kinds of *subject*. While this is partially a product of the way in which international guidelines configure an inverted power relationship between researchers and subjects, I have shown that the fieldworkers’ line of sight was much broader than the restricted sense personhood contained within the category of the human subject. Keeping in view the whole person in front of them, what they considered to be most important about their roles was making people feel valued and included, not only as research subjects but as people more generally. This chapter thus begins to advance the aim of this thesis: to demonstrate how

SATVI's trials have become entangled in people's attempts to craft moral, respectable lives on the peripheries of social and economic life. The next chapter builds upon this picture by adding the perspectives of and interactions between participants and SATVI's clinical teams at the trial site.

## Chapter 6

### Truth, Blood and Respectability: Trial Participation and the Embodiment of ‘Clean’ Blood

One morning in September 2014, I was speaking to Susanna, one of SATVI’s nurses, in one of the side rooms of the ACS building. She was relating to me the story of a young man called Leighton, who had come to the site about a year previously (2013) to undergo screening for one of the vaccine trials being run at the time. The screening visit, as for all of SATVI’s vaccine trials, involved a number of tests and examinations that would determine whether he met the inclusion criteria to be enrolled into the trial (e.g. HIV test, tests for latent and active TB, liver and kidney function – see Appendix 2). However, Susanna noticed immediately that he was drunk, which precluded the possibility of her going further. Trying not to sound judgemental and not wanting to deter him from returning ever again, she said to him, “you must try if you come here again, not to do this, because otherwise our blood results and things, they will be whack”.

The reason Susanna was relating this to me was that one of the participants I interviewed during my fieldwork and who had been part of the Adult Safety Trial for several months at the time was none other than Leighton himself. Susanna informed me, with no small measure of pride, that he had indeed come back again and this time had passed screening with no difficulties. Although Susanna had not conducted the screening visit herself, she had been the attending nurse at the vaccination visit a week or two later. Seeing Leighton looking very different to the last time he had come to the site, she had remarked to him, “oh you look smart today!”. Susanna related to me how she had sat with him during the routine procedures of the visit and said to him:

I said to him, he looks like my brother, actually. And he said “is it?”, and then



I said I loved him so much...but he died of TB. He was my best brother. But his *lifestyle*, his *lifestyle* [her emphasis]. Because it was so painful for our whole family, but I know he [Leighton] can do better. I always tell them they can do better. Do you know who you are? And you're not supposed to do things like that. You can try, you can try. And the next time he come in, and he said "I will do my best".

Susanna, it must be mentioned, was the wife of a pastor, and when she was not working at SATVI helped to their run their well-attended church on Durban Street. This had a significant effect on how she engaged with participants. Nomsa, one of the fieldworkers, jokingly said to Leighton while she was checking his vital signs, "you know that's Jesus over there?!" Whilst everybody was laughing at the time, something clearly left a mark on the man. When I interviewed him, he said that the reason he had initially wanted to take part was to check if he had TB. However, upon passing screening and being enrolled into the trial, something drastic happened:

L: For me, because I didn't even know my status.

JD: You didn't know your status.

L: Ja. I didn't even know if I had been infected with TB. Because they didn't have some people to tell us about those things. If I wasn't not even in the study, I wouldn't know about TB and the things that SATVI is doing.

JD: So you feel that now you're a part of the study, you know your status and you know more about your health.

L: Ja, and also I can tell the people how does SATVI work. Even me, I was doing things that were affecting my health: smoking and drinking. But when I started to attend here, it's when I quit those things to become a normal person because those things go into my blood.

JD: So what was it about taking part that made you decide to stop smoking and drinking?

L: I stopped everything and I became a reborn Christian. So it also helped me because I want to be in this study also to stop these things. Because if I keep on doing that, I'm with God. Because they told me from SATVI when they testing my blood and all those things. So I said, no, I cannot jeopardise my health and jeopardise god, so that means I need to lead my life better.

The interactions between Susanna and Leighton reveal a complex entanglement of an array of phenomena that one might not think would converge in a clinical trial. This includes TB, blood, lifestyle, religion, morality and respectability to name but a few. Although unique in many respects, this case captured fragments of meaning that were present in many interactions and interviews with participants and staff. It will, therefore, serve as a point of reference, a guiding frame in this chapter as we encounter a variety of perspectives and interactions in SATVI's trials.

In the previous chapter, I showed how people who were considered scientifically valuable to SATVI's research were rendered visible as particular kinds of *subject* when being asked to take part in its vaccine trials. This was partially due to the ways in which international guidelines (notably GCP) shape research relationships gravitating around the autonomous, 'universal' human subject. More importantly, the category of the human subject was broadened through the relational work of the fieldworkers, who kept in view the whole person in front of them during consent encounters rather than the restricted, a-relational part of them that appeared on paper. This chapter shifts the empirical focus to the relations between participants and SATVI's clinical teams at the trial site, from screening through to the end-of-study visit often several years later (Appendix 2). The chapter extends the argument of the previous chapter by showing how, within the

inverted, dialogical relationship between healthcare professionals and research subjects brought about by the research environment, both participants and staff brought their own beliefs, values and ideas of proper personhood to bear on what it meant to be a human subject and how this subjectivity was connected to the science. Indeed, in the same moment trial protocols were rendering participants into standardised, commensurable objects of scientific knowledge, on the ground it was people's deepest subjective states, moral agency – even the soul – that were the all-important objects of knowledge and intervention.

A key empirical thread running through this chapter, which reflects the ways in which many people (especially participants) made meaning of SATVI's trials in relation to everyday conditions of structural violence and abjection, are two opposing symbolic associations. The first is the association between TB and 'dirt', one that Kate Abney (2011) has analysed in depth in an ethnography of TB-related stigma in Khayelitsha, Cape Town. This includes dirty *places* and *people*, but perhaps most importantly, as was hinted at by both Susanna and Leighton, dirty *practices* – notably, smoking, drinking, drugs and poor hygiene. In the first part of this chapter, I will build upon Abney's work. I suggest that the connection between TB and dirt is intimately tied to the biomedical moralisation of the disease described in Chapter 3, perpetuating a cycle of blame in which the sick are held accountable for their disease and subjected to stigma. The moral character of TB was, moreover, not stripped away by the objectifying logic of trial protocols but, to the contrary, refracted through and even amplified by everyday scientific practices.

In contrast to the association between TB and 'dirt', SATVI has become known for being in the business of 'clean' blood – drawn, tested, researched and, according to some, circulated among the sick. What is significant about the idiom of clean blood, I will suggest, is firstly the tangible, contiguous and symbolically rich way in which it

positions the relationship between individual gifts and community benefit. Secondly and perhaps more importantly, it is the status and responsibility that it confers upon participants. In the introduction to a collection of papers entitled “Blood Will Out”, Carsten (2013) proposes a renewed anthropological emphasis on blood because of its uncanny ability to accrue layers of symbolic meaning. One theme that the contributors show to recur time and again is the notion that blood is “the stuff of truth...morally, personally, politically and medically” (Carsten 2013, p. S13). In her own article, Carsten (2013b, p. S130) examines a politically charged incident in Malaysia where a blood sample taken from a leader of the opposition “was claimed by some as having the capacity to ‘reveal the truth’ about his character”. Focusing on clinical pathology labs and blood banks, she shows just how difficult it is to separate the social from the scientific and that, when it comes to blood, there is the ever-present possibility of them collapsing into one another (2013b, p. S130).

Using this intriguing notion of blood as the ‘stuff of truth’, I will show that to be someone of ‘clean blood’ is a state that is at once biological and moral, compelling participants to adopt or maintain a healthy, respectable lifestyle and avoid ‘dirty’ practices associated with TB. Participation for some participants, such as Leighton, could be a transformative, even evangelical journey, a process of responsabilisation that went far beyond the requirements of protocol – so far that it even conflicted with the epistemological purposes of the trials (cf. Brives 2013). Being with SATVI, I will ultimately argue, conferred upon participants a powerful form of symbolic capital, casting SATVI alongside other spaces, strategies and institutions in which people struggle back against the inscriptions of the state to emerge as moral, respectable individuals (Jensen 2008; F. Ross 2010). At the same time, the figments of the ‘problem TB patient’ and the *skollie* lurked in the shadows, always threatening to rear their heads and had to be

continually worked against by participants and staff alike (Jensen 2008). The flip side to such morally charged understandings of trial participation was the dejection and shame that could come from exclusion, which is often overdetermined in a region rife with TB and its associated challenges.

### A Note on Quotations

Direct quotes from my interviews with trial participants are followed by basic demographic information about them, as defined in Table 1.

Shorthand order	Demographic	Abbreviation /units	Explanation
1	Age	Years	—
2	Gender	M F	Male Female
3	First language	A X	Afrikaans isiXhosa
4	Vaccine trial	ST ET HIV-EI	Adult Safety Trial Adult Efficacy Trial HIV-Exposed Infant Trial

**Table 1: Shorthand used to describe participant demographics**

For example, (43, M, X, ST) is the shorthand for a 43-year-old male whose first language is Xhosa and who was participating in the Adult Safety Trial. All participants under the age of 18 were in the Adolescent Trial and therefore no trial designation will appear in the text for these younger participants.

### TB and ‘Dirt’

The vast majority of the participants that I interviewed were from either the Afrikaans-speaking low-income suburbs of Worcester, including Roodewal, Riverview and Avian

Park, or the Xhosa-speaking township of Zwelethemba. Speaking to them over coffee or Coke, I was interested to hear a little about their lives. Of the 65 adults I interviewed, approximately 40% were unemployed<sup>25</sup> and the remainder, with one or two exceptions, were typically employed in low-earning, often unstable jobs such as domestic workers, farm hands, factory workers, shop assistants and home-based carers (see Appendix 3 for socioeconomic indicators). While some were quite shy, especially those who had not been in the trials for long, most were very talkative and were quick to relate to me the challenges associated with living in post-apartheid Worcester. Gangsterism and drugs, in particular, were spoken about with great resentment. The adolescents, it seemed, were especially affected by the gangsterism and violence, often having to stay inside after school hours because of the dangers of being outside when things got 'lively' in the evenings. Several of the young men I spoke with had faced considerable peer pressure to join gangs themselves, and even school was no reprieve because the gangs operated in the schools, with violence frequently breaking out.

In addition, almost every single participant had known someone with TB, be they family, friends, neighbours or colleagues. Some had witnessed seemingly miraculous recoveries after only a few weeks of treatment. Others, less fortunately, had watched as their friends and family slowly declined, were admitted to hospital (usually Brewelskloof) and sometimes even passed away.<sup>26</sup> With such intimate experiences of the disease, at first I expected people to point towards structural factors like poverty, cramped housing and poor nutrition as drivers of the TB epidemic, which Farmer (2000) has highlighted using ethnographic illness narratives (see also Harper 2006, 2010). While this was partially the

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<sup>25</sup> It was not always contextually appropriate during interviews to ask about people's employment status. I derived the figure 40% from those whom I was able to ask and from the average unemployment rate for the trial in which they were participating.

<sup>26</sup> It was not lost on these participants that we were speaking but a few metres from the main hospital wards where their loved ones had spent several months and possibly even died.

case, people's understandings actually resonated strongly with the biomedical discourse around TB and arguably amplified its orientation towards individual responsibility and blame. To capture the richness of what participants expressed to me it is useful to turn to Abney's (2011) thesis, *Whoever Said a Little 'Dirt' Doesn't Hurt?*

Based on her work in Khayelitsha, Cape Town, Abney (2011) shows that TB was thought of by residents primarily in terms of the organising metaphor of 'dirt' (see also Douglas 1966). Most people, for instance, thought that the reason there was so much TB in the township because it was 'dirty', in contrast to the 'cleanliness' of wealthier, mainly 'white' areas such as Somerset West (Abney 2011, p. 33). Similarly, a number of the participants that I spoke to explained the prevalence of TB in Worcester in terms of dirt: "Riverview is very dirty. I suppose it's because of that, and the insects" (21, F, X, ET). Puddles of dirty water, urine and other substances also featured in people's explanations. The association was actually most apparent when I was walking around community settings in Worcester while I was helping with an anthropology student field trip.<sup>27</sup> Residents were understandably reserved about the subject of TB and, when they were happy to discuss the topic at all, were quick to distance themselves from the disease. This was either by proclaiming that they were 'clean' of TB or by pointing us towards 'dirtier' parts of the township to find out more. For example, one resident said, "No, you won't find any TB *mense* [people] here but go to town on the other side there by the bridge...It's riddled with TB *mense*, lots and lots" (Field Report, Sofia Ribeiro).

'Dirt' was, to be sure, a metaphor for poverty. However, Abney found that 'dirt' was not only an attribute of living conditions and (coloured) bodies but also located in

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<sup>27</sup> This field trip took place between the 24<sup>th</sup> and 26<sup>th</sup> April 2015. The trip was part of a third-year methods course at the University of Cape Town (UCT), and the specific task of the field trip was to find out what residents thought about TB and SATVI's work. The main deliverable for the course was a field report. In this chapter, I use a number of quotes from the student reports, for which permissions have been obtained from UCT's anthropology department and from students themselves. The name of the student is provided.

*practices*. She observes that “doing bad things to one’s body”, including “sharing cigarettes with someone who has TB” and “drinking too much” were perceived as key drivers of the epidemic (2011, p. 50). Not only were my findings consistent with this but, moreover, drinking, smoking, drugs and poor hygiene – which gave rise to some of the most evocative images of ‘dirt’ – were, by some distance, the most frequently cited reasons that TB was spiralling out of control in Worcester. Included below is a collage of quotes to give a snapshot of people’s reflections:

A lot of people get TB. I’ve never had TB. And often it’s also people’s own doing, because hygiene plays an important role in one’s life, and often we don’t want to do these things. So we leave things dirty or something like that, and that’s also part of...or I pick up a germ from people who spit in the road.

(15, M, A)

JD: Why do you think TB is such a problem in this community? What would you say is the main cause?

R: The smoking and the drinking. They smoke with everybody and they drink with everybody. It’s there where the TB comes in. They don’t smoke alone. Maybe I’m sharing a pipe with you and so on, or I drink something and then maybe I pass the glass onto you and you drink out of the same glass. Or I have TB, but now I don’t tell you that I have TB, so it will spread. Maybe they are spitting here, then your child walks past and then she picks up that germ.

(42, F, A, ST)

There’s one guy in a flat in River View, he’s got TB and he’s not bothered. He doesn’t take his medication. He’s just hanging around on street corners



and using drugs. He couldn't care. He's just hanging around there. Now he is going to infect the next person. He is now going to spread that germ, but he could have prevented that by taking his medication. Now he's just carrying on.

(33, F, A, ST)

In Chapter 2, I showed how TB has become highly moralised in biomedical discourse, with blame for the continued proliferation of the disease deflected away from structural conditions and onto afflicted individuals and communities (Farmer 2000; Compion 2008). The notion that people “don’t care” was common among nurses, especially in their more frustrated moments, which sometimes took on a Christian inflection to the effect that a lack of responsibility was tied to an impurity of heart (Marks 1997; Hull 2009). What we can see emerging from people’s descriptions above is the stereotypical figure of the ‘problem TB patient’ (see Chapter 1, p. 21), one which draws upon but perhaps even intensifies the orientation towards individual blame by focusing attention on people’s ‘dirty’ practices. Jensen (2008, p. 11) observes that one of the most powerful ways in which “structures of dominance are reproduced”, in his case the stereotype of “problematic colouredness” (ibid, p. 183), is when the residents themselves start pointing fingers at one another to lay claims to respectability. I would suggest that TB, so prevalent and morally charged as it is, constitutes an important site of social reproduction of governmental stereotypes, both the ‘problem TB patient’ and the partially overlapping stereotype of the *skollie*. TB is neither an abstract, asocial biomedical category nor simply a function of structural violence. Rather, it is intimately connected to the practices that people found most abhorrent.

### **“In my Life it is not Money that is Important, it is...”**

One of the questions that I built towards with participants was: why did you decide to take part in a vaccine trial? People’s motivations were diverse, overlapping, multiple and sometimes shifting. Overall, three main categories of motivation emerged – the same three, in fact, that were identified by Abrams et al. (2011) in a pilot study involving adolescents in one of SATVI’s earlier vaccine studies. These were altruism (40 participants or 41%), health benefits (59 or 60%) and money (16 or 16%) (see Table 2 for a detailed breakdown across the four trials). These figures, while not revealing much by themselves, are useful to orient the following exploration, and this chapter and the next will gradually unpack them and see what lies behind the numbers. The category of ‘health benefits’, cited by the majority of participants, is explored both in this chapter and the next, the latter of which discusses comparisons and connections between SATVI and the government clinics (Chapter 6). This chapter, meanwhile, explores all three.

<b>Vaccine Trial</b>	<b>Altruism</b>	<b>Health Benefits</b>	<b>Money</b>
Adult Safety Trial (n = 26)	10 (38)	22 (85)	4 (15)
Adult Efficacy Trial (n = 27)	15 (56)	12 (44)	5 (19)
HIV-Exposed Neonate Trial (n = 12)	0 (0)	12 (100)	1 (8)
Adolescent Trial (n = 33)	15 (45)	16 (48)	6 (18)

**Table 2: Breakdown of participant motivations n (%) across trials**

When I say that this chapter will explore all three, this does not mean keeping them analytically distinct in the a priori way that they are in the bioethical literature. Altruism, in particular, holds greatest moral legitimacy in research ethics and thus tends to be held at arm’s length from health benefits and money, both of which point towards the possibility of ‘undue inducement’ and are therefore regarded with caution (see Geissler

2011). One problem with this division is that it positions health benefits and money as indicators of ‘vulnerability’ in advance of hearing from participants themselves how they conceive of what constitutes morally legitimate and illegitimate reasons for taking part. In the emergent moral economy that I found surrounding SATVI’s trials, distinctions between legitimate and illegitimate motivations were certainly drawn and resolutely policed. But interestingly, both altruism and health benefits were deemed equally morally praiseworthy and in fact blurred together in the idiom of ‘clean blood’ that will be introduced shortly. Perhaps the most illuminating pathway into the moral economy to which I draw attention is by starting with what participants claimed *not* to be motivated by and which they would go to some lengths to disassociate themselves with: money.

During interviews, where it felt appropriate I asked participants whether they considered the R150 that they received at each study visit to be a significant amount of money and, moreover, whether it influenced their decision to take part. One reason for this was that, as we saw in the previous chapter, for the fieldworkers the money featured prominently in their day-to-day work, seemingly lubricating the wheels of the recruitment bandwagon. Contra the Medicine Control Council’s formal position that R150 was but a ‘reimbursement’ for lost costs (Ballantyne 2008; Geissler 2011; Resnik 2015), almost everyone I asked directly about the matter (28 out of 31 or 90%) said that the regular receipt of R150 was a modest but nonetheless important contribution to household income: “Like the child must eat porridge in the morning before going to school, so maybe it can buy flour when there isn’t any flour. So, it does fill the little gaps, you understand?” (33, F, A, ET). However, despite this, very few participants saw money as a motivator, and in the instances that it was (16%), it tended to be a background consideration (the distinction between background and foreground is not reflected in Table 1). In fact, often without raising the topic of money myself, participants consciously

*distanced* themselves from the notion that money was responsible for their taking part, and it was uncanny how common this was expressed as follows: “For me it isn’t about the money. What is it to give to someone and you can save a life?” (18, M, A, ST); “In my life it is not money that is important, it is my health” (40, F, X, ET). Especially when health was invoked, people pointed towards their chests, emphasising the distinction between material gain and that which was important to them.

Interestingly, in the same moment that participants framed themselves as taking what they considered to be the moral high ground, they also stated that the money was the most pertinent factor motivating *other* people. Moreover, it was with morally questionable intentions with which other people sought money from SATVI, especially to fuel drinking or drug habits – the ‘dirty’ practices with which TB was associated. I was speaking with a woman from Riverview Flats:

JD: How did you hear about SATVI?

R: Friends of mine.

JD: And what did they say? Were they positive?

R: Actually, most of them went for the money. Because I said to them, that’s not right, you have to help people. You just go for the money. Some of them are doing drugs, so that’s why they went for it. So I asked them, why don’t they take people like me who really want to do it? And so last time it was...what’s her name...[Susanna]...because I told her and she said, okay, fine, she’s going to put my name on the list.

(44, F, A, ST)

Finding a way of explaining this radical distinction between the morality of self and the questionable intentions of others – that nobody and everybody was taking part for the

money – caused me much grief in the writing of this thesis. But gradually, and especially upon realising that it was mostly coloured participants who endeavoured to build these walls, I came to the conclusion that perhaps the best lens through which to view the situation was in terms of Jenson’s (2008, p. 8) observations regarding the dual consciousness of colouredness (see Chapter 1, p. 35). Living in the shadow of their own governmental stereotype, people had to cast it aside to reveal their own morality, displace the shadow on to others and elsewhere. This was very similar the ways in which TB and its spread were located in (other people’s) ‘dirty’ practices.<sup>28</sup>

While illuminating, speaking about people’s motivations can only take us so far. What they are part of and hint towards, I believe, is a broader moral economy repudiating the ever-present threat of ‘dirty’ practices from spilling over into the *ordentlike* (respectable) space of SATVI’s trials. But before we explore this further, it is useful to speak briefly about how practices such as drug and alcohol abuse – some of the main indicators that someone was in it for the ‘wrong’ reasons – was handled in SATVI’s trial protocols.

Excessive consumption of these substances was, on the whole, guarded against. Phase I studies such as The Adult Safety Trial, for instance, involved a drug test as part of screening. It was also standard practice to have questions regarding drug and alcohol consumption as part of the health questions at screening visits and throughout trials. However, it is not for immunological reasons that these substances are generally frowned upon. Rather, it makes for *unreliable* participants: they are less likely to attend all follow-up visits (although the possibility that the R150 reimbursements might help subsidise a drug/alcohol habit questions this notion somewhat). When it comes to proving the

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<sup>28</sup> The phenomenon of ‘othering’ the negatives as a way of bolstering fragile and threatened identities is a widespread phenomenon. One recent example that springs to mind is Brexit, in which ‘foreigners’ are blamed for the societal ills of the United Kingdom.

efficacy of a new vaccine, participants' scientific value resides in a disposition to develop TB, which is only heightened by substances that affect their immune system. In fact, SATVI's trials are powered based on the region's extraordinary TB incidence, inseparable from which are the region's high rates of alcoholism and drug abuse (Health Systems Trust 2004; Compion 2008, p. 28). Therefore, so long as a potential participant appears reliable, trial protocols can quietly accommodate – and can do little about – such practices. By contrast, the moral economy inhabited by participants and staff danced to a different tune, one that defied the passive acceptance of the status quo embodied in trial protocols and even ran into tensions with the trials' formal epistemological aims, as I will suggest later. Let us now return to where this chapter began, with Susanna's interactions with Leighton.

### **'Looking' Beyond What You 'See'**

Speaking with Susanna, she explained to me that, in her work with the church, she was accustomed to people coming through the doors looking for help and spiritual guidance, who were often deeply unhappy about their lives and circumstances, which sometimes led them to alcoholism, drugs and gang life. Counselling them, explaining to them that they were valuable in the eyes of God and, more generally, trying to instil in them a hope for better despite their often-destitute circumstances, was a large part of her life beyond SATVI. Through this church work, she was very well known in Worcester and knew the people in turn: "Because I grew up in Worcester, I know a lot of them, and they know me...When they go home, and I pass them and they say, isn't that the pastor's wife?" This meant that she was well acquainted with the social and economic challenges faced by Worcester's constituents and often already knew participants and/or their families.

She went on to explain that she found it impossible to vacate her role as church leader when coming to SATVI:

For me it blends in. The church, and my work, it blends in...Everyone who comes in here – I don't know if it's because my husband is a preacher – but I see them as someone valuable. That's how I see them. If they come in here, I will never see you as a participant, you're valuable to me. So for me I'll never ever see you as an object [sic]. I'll see you as, you have a soul. You know I always said, the reason why you are here, and what does God say about why you are here, you were created.

The close historical relationship between Christianity and biomedicine has been a recurring theme so far in this thesis, especially among some of the government clinic nurses who used it to make sense of and allocate blame for the seemingly biblical scale of the TB epidemic (Chapter 4). Here, Susanna's remarks can be seen as a way of expressing through a Christian lens a well-documented tension that stems from moving from a healthcare-professional patient relationship to a researcher-subject relationship (described in Chapter 3). That is, between the abstract and distanced logic of trial protocols – where participants are treated as objects of experimentation and data collection – and the needs, expectations, and subjectivities of those with whom researchers actually interact (Easter et al. 2006; Fisher 2008; Timmermans 2010; Simpson & Sariola 2012). For Susanna, people had an inherent value as created beings, with a purpose that vastly transcended the category of 'participant'. She felt it important that this was recognised, not only by herself but among her colleagues too: "For that, you know I normally watch that the other staff will also treat the participants the correct way, I'm very strict about that. They're a participant, but please look at them beyond what you see". Thus, while trial protocols were shaping participants into measurable, commensurable bodies, on the ground it was the moral agent (or the soul) that was the all-important object of knowledge and intervention.

Susanna's approach to participants is similar to the way that other research staff approached participants too. As we saw in the previous chapter, the fieldworkers went far beyond what they needed to do in order to convey to participants that they were valued and needed, not simply for science but as human beings. Some fieldworkers expressed this through a Christian lens like Susanna, and often prayed with people in their homes. The nurses, too, used their knowledge and experience to do what they could for participants within their capacities as researchers. With time to develop relationships with participants in a way that is often impossible in the chaos of a government clinic setting, almost all the nurses said that they got to know participants and often offered them advice (Easter et al. 2006). Dayna, for instance, said that the research environment was ideal for instilling a sense of responsibility and empowerment:

It [research] taught me to still try with my participants to give a sense of responsibility and empowerment, whereas in the clinic nobody cares and people are starting to give up. I still have that drive. And this is a good place for encouraging good health, responsibility, and lifestyles.

While Dayna suggests that the government clinic staff have started to “give up”, she and other nurses who had previously worked in the clinics also used SATVI as a platform from which to advocate the clinics and to counteract people's overwhelmingly negative perceptions. This we will discuss in the next chapter.

The way that Susanna used her time with participants, similar to Dayna's sentiments regarding responsibility and lifestyle, was to counsel participants at length where the opportunity presented itself:

I will sit, I will do what I must do, then if there's time – I know it's busy – I will counsel them, have long discussions with them. But I know who you are,



and I will treat you like that. So if you go, I'm sure that you will come back again. For *that* reason [her emphasis; read: not for the money] And you will tell the others outside...And the next time, when they come in here, you can see there's a difference, there's a change. Because they won't come in here like, *dirty* again. They will try to be *better*. Really, you can observe that.

Prior to her counselling them, there was certainly a chance that they would return time and again – but for what she considered to be the ‘wrong’ reason, that is, for the money. However, upon engaging with them, she believed that she often had a profound impact upon them such that they would return to SATVI again, but for a *different* reason, one that was not grounded in material gain. Most telling was her phrase, “they won’t come in here like, *dirty* again”, subtly indicating the kinds of ‘dirty’ practices for which money from participation was thought to be used. Leighton, in particular, reminded Susanna of her brother who had died from TB as a result of “his lifestyle, his lifestyle. Because it was so painful for our whole family, but I know he can do better”. Susanna, in short, used her research work to reach out to steer them towards ‘better’ lifestyles, away from the ‘dirty’ practices that might have led them through the door in the first place.

In this section, I hope to have shown that the movement from a nurse-patient relationship such as that found in a government clinic to a researcher-subject relationship does not amount to the stripping away of care. In fact, similar to the findings of other anthropologists and social scientists, it appears that the particularities of a research relationship actually engender novel possibilities for engaging with people (e.g. Easter et al. 2006; Fisher 2008; Timmermans 2010). Certainly, Sister du Plessis, as we saw in Chapter 4, was desperately trying to find such a way to reach out to people in Worcester, especially those who live in the houses and streets of ‘unruly’ TB patients. What I would like to take forward into what follows is the sharp sensitivity to drug abuse, alcoholism

and other ‘bad’ lifestyles that went beyond the narrow requisites of trial protocols. While participants were often thought to have come to SATVI in the first place for one reason, through interventions upon an object to which protocol was blind – the soul, the person etc. – the belief was these individuals might come to view participation in a new light.

### **Donations of ‘Clean Blood’**

Leighton, as we saw above, was clearly influenced quite profoundly by his interaction with Susanna and the trial of which he became a part. Not only did he decide to quit smoking and drinking; this also corresponded with a conversion to Christianity. But we might note that, while Susanna only made passing reference to me about the drawing and testing of blood samples – “...otherwise our blood results and things, they will be whack” – for Leighton this held considerable significance. For him, he quit smoking and drinking at least partially because, as he put it, “those things go into my blood”. While Leighton’s case was unique in many respects, his interpretations of the trial resonate strongly with how many other participants – and indeed some research staff – made sense of SATVI’s trials. Thus, before returning to Leighton’s conversion, here I explore the significance of blood as a site of meaning-making and draw attention to one prevalent set of meanings in particular, one that stood out because of its symbolic richness and moral valence. This is the notion that SATVI is in the business of ‘clean blood’.

As the research institute’s name suggests, TB vaccines are SATVI’s *raison d’être*. All research activities are, in one way or another, oriented towards the ‘greater good’ of a new vaccine. Yet for those on whom research was conducted, vaccines made a fairly limited appearance: they were administered once (sometimes twice) at the beginning of the trials and then never again – although research staff observed closely for adverse events. Many people would not even pass screening and therefore receive a vaccine. Blood draws, by contrast, were arguably a far more ‘visible’ presence during trials. Every

person who visited the field site to enrol in a trial had their blood drawn at least once. Moreover, should they pass screening and be enrolled, their blood was drawn at intervals throughout the trial, through to the end-of-study visit often several years later. With this in mind, when I asked the 40 participants who had expressed altruistic motivations how they understood their role in SATVI's research, 18 (45%) explained their participation in terms of 'donating blood' (the majority of other responses involved either vaccines, notions of 'protection' or gave less away with phrases such as "helping others"). Moreover, many other participants with alternative motivations, especially health benefits, mentioned either explicitly or implicitly an importance of their blood to SATVI's research efforts.

Conceptions of what blood donation entailed varied considerably from participant to participant. It was difficult, at times, to discern whether participants thought that research was being done on their blood, or whether they believed that it was being transfused directly into the bodies of the sick. But given SATVI's association with TB, donations were often expressed in relation to TB patients:

JD: What was your personal reason [for taking part]?

R: Oh, my personal reason. When I look around me and see the people in my community getting sick with TB, that was my reason, there are many people who are suffering and who have TB, so what is it to me, who is one of the healthy ones, just to help by donating [blood].

(33, M, A, ET)

In my thinking...this blood of mine is going to the people with TB, because they need blood.

(24, X, F, ET)

Others were less specific about TB in their explanations. For instance, one adolescent I conversed with said: “I like to give blood to people who need it” (14, M, X). In addition, some participants used the notion that they were giving blood as a starting point from which to position their own role in the community as moral and respectable individuals in relation to the moral failings of others. For example, one lady expressed that her participation was connected to her being a role model and caregiver for children who were not looked after well by their parents:

JD: So how do you see yourself helping others?

R: Okay, it’s actually about giving my blood to other people, and that can help and save them...And I love my children...not actually just mine...any children, I love them. All the children there in the A-block and B-block where I live [Riverview Flat Blocks], they call me mummy. You see, it’s because I have a heart, and I don’t talk like their parents or other people talk to them. Because most of them don’t talk nicely to their children. And as a person and a mother, you must be a role model for a child. And that’s what I am in the community there by our side.

JD: And so do you think that being part of the SATVI study here is a part of that role for you?

R: Yes.

(44, F, A, ST)

From an abstract bioethical standpoint, that blood donation was such a prevalent understanding of SATVI’s trials might raise alarm bells because it easily falls into the category of ‘misconception’. However, I contend that it should not be delegitimised and dismissed as a mere ‘misconception’ but rather be viewed as a conceptual solution to the abstract bioscientific notion of how individual participation can translate into positive

community health outcomes. Whereas the scientific conception of a vaccine trial was vague at best to most participants (not a single participant explained SATVI's research as such), blood was something that people *knew*. It was something that they found relatable and had experience with, for instance in healthcare settings, in the work of the blood transfusion service<sup>29</sup> and in religion (explored below). Blood provided a hermeneutic 'point of entry' into the science; it allowed people to pull things in and make sense of the trials in a way that was arguably not available to them through other means. It was telling that those who expressed their role in the trials in terms of vaccines tended to do so hesitantly. Those who spoke the language of blood donation, by contrast, usually did so confidently and with considerable clarity.

What is significant about the blood donation, however, is not only its destination but also what it says about the people from whom blood is drawn. It was observed above that, insofar as efficacy trials are concerned, participants' scientific value resides in a disposition to sickness, that is, a certain probability of developing active TB (approx. 1.5/100 per participant per year). However, conceived in terms of blood donation, participants' value to SATVI, to the contrary, resided in being and staying *healthy*. During interviews with participants, several expressed to me that, it was only once blood had been screening for disease that it could be circulated: "Me, blood that is taken...for sure is checked that it is right, and then it will support those people who need" (20, F, X, ET). There was, in fact, overlap between health-related and altruistic motivations for taking part: "I have also joined because you know more what's happening to you and your health. You learn more. And it is good to donate blood for someone else and so on" (33, F, A, ET). But perhaps most interestingly, I began to notice in both community settings

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<sup>29</sup> The South African National Blood Service (SANBS) is a familiar presence in Worcester, and a few participants stated that they had donated blood to SANBS themselves. During my fieldwork, I often saw the mobile clinics of the Blood Service at Brewelskloof hospital.

and interviews that the blood needed to be ‘clean’. Perhaps the most aptly expressed example emerged during the aforementioned field trip, when one group of students were talking to a mother with three children, all *four* of whom were currently enrolled:

I asked her if she has heard of SATVI and then she said yes, she and all three her children were involved in the programme. I asked her to explain what SATVI did, she explained that they “take your blood”, it’s a kind of “donation” of blood. She didn’t know what exactly they do with the blood, but she knew the blood had to be clean blood. So if you are involved with SATVI you know you are healthy. She also went on to explain that they were particularly interested in getting school children’s blood because it was “clean”.

(Field Report, Terena Koster)

The remark about children’s blood being clean was particularly revealing. For it conjures images of purity, innocence and perhaps being untainted by the ‘dirty’ practices usually associated with adulthood, for instance drinking, smoking, drugs or sex. This was, potentially, reinforced by some of the associations drawn by SATVI’s staff between these practices and the drawing of blood. We saw above, for example, that Susanna told Leighton that he should not come to the site whilst drunk lest it be reflected in the blood work. One of the fieldworkers, Peter, even told participants and their parents they should not to take drugs because it affected their blood:

And when I speak to the participants and parents and all this, I’m actually also telling them that, don’t use drugs. Don’t do that, because we as SATVI and the research we don’t want you to do that because we need your blood, well you as a person, so don’t do that.

The picture that is therefore beginning to emerge is that the blood draws that lay at the heart of participation for many did not only reveal diseases. They also, importantly, acted as a window into lifestyle and a signifier of morality. In other words, there was a tight connection between doing good to for the *community* and being *good* oneself. It is in this regard that, following Carsten (2013a), it becomes useful to view blood as “the stuff of truth”. Like the example of the Malay politician explored by Carsten (2013b), so too SATVI was believed to have the capacity to see the truth about people’s moral agency, with only the ‘clean’ being edible to enter and continue donating blood in the trials. We might even see SATVI’s trials as enacting a kind of simultaneous medical and moral triage, wherein not only biological but also moral states become known through the process of drawing and testing of blood. This notion will be explored in the following section, where we revisit Leighton’s interpretations of his interaction with Susanna and the trial.

### **Trials as Moral Triage**

Leighton, like many participants, said that he decided to take part in the first instance “because I didn’t even know my status”, by which he meant whether he had TB. However, upon finding himself to be TB-free, he underwent a profound transformation. Having explored both Susanna’s way of engaging with participants and the associations between SATVI and ‘clean blood’, we are now in a position to revisit his journey. What I will suggest in this final section is that Leighton’s interpretation of Susanna’s Christian message was refracted though and even amplified by the idiom of ‘clean blood’, connecting Christianity and medical science in interesting and unexpected ways. At the same time, Leighton’s narrative draws attention to the fragility of positive lifestyle changes in a destabilised and impoverished setting such as Worcester.

The conversion of Leighton resonates very strongly with Jenson's (2008, p. 181) ethnography in the 'coloured' township of Heideveld, where he showed that religion was used by young men seeking to leave gang life as an "embodied strategy of self-improvement". Leaving a gang was terribly difficult, and claiming to have departed from gang life was not enough: one had to demonstrate, repeatedly, to both gangsters and polite society alike, that one had truly left. Jensen spoke to one young man called Shaun who, in addition to apologising to those he had wronged, pointed towards the embodied practices that had had to adopt to instil trust:

If you are a Christian and carry a bible, then you can get out, but not by yourself. You must be a Christian in their eyes. You mustn't smoke. You mustn't drink. Walk with a suit and your bible, and they will see that you are a Christian. That is why they won't touch you.

(Jenson 2008, p. 182)

All the while, people were "watching his every move for traces of what was presumably was always already there...the paradox that faced all coloured men from the townships as they staked their claims to respectability" (ibid, p. 183). I would like to view Leighton's conversion in the same light as Shaun's, but argue that it is, if anything, even more powerful as a 'strategy of self-improvement' because of the very close intertwining of religion, participation, blood draws and lifestyle.

On first glance, it seems odd that the supposedly mundane, bioscientific practice of drawing and testing blood might find affinity with Christianity. However, Carsten (2013a), in fact, supports her depiction of blood as the "stuff of truth" by drawing attention to a long history of this conceptualisation of blood in Christian thought. In the same volume as Carsten, Bildhauer (2013) finds in Medieval texts the reoccurring notion that blood that is rendered visible has the ability to reveal people's innermost states,



including truths about both their health and their moral propriety. Carsten (2013a, p. 8) adds that these ideas are themselves partially derived from biblical writings, for instance Leviticus (17:1-15) which depicts blood as “both the animating life force and the bearer of the soul”. SATVI’s blood draws – which for many constitute the “beating heart of the trial” (Brives 2013, p. 398) – might, therefore, be read as an act of making blood visible, revealing both biological and moral states. This is not to suggest that Leighton had been reading Leviticus - although he may well have been exposed to these ideas in the symbolisms and rituals of church. Rather, it is to say that there is a considerable amount of conceptual room for a turn to Christianity to happen in conversation with ‘mundane’ bioscientific practices.

Susanna might have been committed to ‘looking’ beyond what she ‘saw’. But from where Leighton was sitting, this was aided by the drawing and testing of blood, offering a particularly powerful means of *looking* and *knowing*. SATVI would, in effect, know exactly what he had been doing in and between his visits to the site, whether or not he told them. This was suggested in the following excerpt from our conversation, after he expressed how he felt about finding that he did not have TB:

I never knew how healthy I was. Even now when I’m out there in the community, I know my status. I know I’m a hundred percent cure. Nothing is wrong with me...I don’t have fear when I’m walking there because I know I’m healthy a hundred percent. Because now I’m over the weekend. A lot of things are happening on a weekend. People are drinking beer, partying and all those things. Because I know I’m a part of SATVI, I don’t belong in those things. I must keep my body healthy, and I must come Monday and they would...Today the results when they have come.

Being a part of SATVI, he suggests, he could no longer take part in some of the things that he did before, particularly “drinking beer, partying and all those things”. In fact, for Leighton, following protocol – conceived of as not partaking in ‘dirty’ practices – was akin to following the word of God. Hence in the opening vignette, he says: “I want to be in this study also to stop these things. Because if I keep on doing that, I’m with God”. Perhaps I am not going too far as to suggest that it is almost as though a church preacher had the remit to draw and test blood as an act of religious confession. That is, in effect, exactly what was happening when Leighton came for follow-up visits – an extension and indeed amplification of religious authority through a bioscientific experiment.

Here we can begin to appreciate the power of trial participation as an embodied technique of self-improvement. One had to really *be* someone of ‘clean blood’ to stay in the trial – at least, according to this interpretation of SATVI’s work. In the same moment, this also conferred upon Leighton and others like him a powerful form of symbolic capital, a robust marker of respectability that could be worn on one’s sleeve. It might be noted that clinical trials are often lamented in the social scientific literature for being so *short*, a critique which certainly carries weight in terms of life-saving medications (e.g. Geissler et al. 2008; Petryna 2009; Kelly 2011; Nguyen 2011). But in a context where, as Fiona Ross (2010, p. 5) observes, *any* kind of stability is hard to come by, two-to-three years of trial participation is a comparatively long period, one in which one can receive attention, support and even small amounts of money along the way. It is no wonder that SATVI has become an important part of the landscape of hope and moral aspiration in which people in Worcester strive to overcome this seemingly unsurmountable stereotype.

Leighton, as he suggested, no longer belonged around people who engaged in certain kinds of lifestyle. Yet at the same time, he said that he – and other participants

who I unfortunately was unable to speak with – tried to convince other people to join SATVI and undergo the same kind of transformation they went through:

JD: So you stay away from those people.

L: And when we are around them we try to tell them about SATVI. They are scared because they are not fine with...because the blood tells you more about yourself.

JD: Okay, so they are afraid that they are going to hear about...

L: The things that they are doing.

The problem he experienced in this was that people were often less willing to hear about ‘themselves’ than he. Studying HIV surveillance in KwaZulu-Natal, Reynolds et al. (2013) suggest that the ‘gift’ of blood in medical research is in many respects a poisoned one. They show that, while the research might be construed in terms of community benefits, blood samples contained “dangerous knowledge”, eliciting fears of its circulation (2013, p. 122). Similarly, in the SATVI context, the truth-bearing capacities of blood were such that they could reveal not only positive and health-affirming truths but also negative and potentially stigmatising ones. Indeed, the truths revealed by blood can be read to go beyond the biological to the very essence of personhood.

With this cooler theme in mind, it is important finally to consider that, whilst trial participation might constitute a particularly powerful strategy of self-improvement, success was far from guaranteed, even for the ‘initiated’. Although I was largely unable to talk to people who left the trials, I received hints that some people felt unable to return to SATVI in the wake of ‘deviations’ from the lifestyle they felt was required of participation. Leighton said that he knew people who had not ‘made it’ through the trial: “they are not making it because every time you are here, you are being tested, so it tells you about what we are doing in past days since the last time that you were meeting”. In

addition, some of the students during the anthropology field trip encountered an Afrikaans-speaking man who said that, while his blood was ‘clean’ upon entering SATVI’s trials, ‘dirty’ practices subsequently ended his participation:

*“SATVI het my blood gebruik. Maar nou is my bloed vuil, ek doen ander goed wat maak dat my bloed nie meer skoon is nie.”* (SATVI used my blood. But now, my blood is dirty; I partake in other things that cause my blood to not be clean anymore). Tylor asked him if he could tell us what these ‘things’ were that caused his blood to not be clean anymore, and he just smiled and simply stated: *“Sommer net dinge”* (Simply just things). We both could see that he did not want to elaborate on the situation.

(Field Report, Kylie Opperman)

In many ways, this (ex-)participant’s remarks to the students captures everything this chapter has suggested about the idiom of clean blood: that SATVI was “using” his blood, that this blood had to be “clean”, but that he had engaged in “dirty” practices which had subsequently ended his participation. What is noteworthy is that, insofar as trial protocol was concerned, he would certainly not have been excluded because the quality of his blood had been compromised by drinking, drugs or whatever else. It is, in fact, possible that he was not formally excluded at all but simply felt too ashamed to return again, which was perhaps suggested by his responses to the students. But even if he was excluded – perhaps because he developed TB or another medical condition – the way he understood what exclusion meant was evidently not in the amoral, matter-of-fact way of a trial protocol. Rather, it was perceived as a personal moral failing. This only goes to emphasise the great weight that could be placed upon people’s shoulders when people entered SATVI’s trials and the dejection and shame that could come when they were found wanting.

## Conclusion

By following the interactions between Susanna and Leighton, this chapter has drawn attention to the ways in which both research staff and participants made meaning of SATVI's trials and made them relevant to their lives and circumstances. Although people's motivations and interpretations were diverse, multiple and shifting, what crystallised through these everyday scientific encounters is a moral economy that operated according to a different logic to vaccine trial protocols. The trial protocols were partially resigned to alcoholism and drug abuse among study cohorts. By contrast, this moral economy involved a sharp resistance to practices considered to be 'dirty' as people brought their own beliefs, values and ideas of proper personhood to bear on what it meant to be a human subject. For research staff like Susanna, this entailed not simply viewing participants as objects but rather as people of inherent worth, and in which the all-important object of knowledge and intervention was not the body but rather the person, the moral agent and even the soul. But this was taken further by participants themselves, because the logic of 'clean blood' collapses the subject-object distinction altogether, intimately connecting internal states and bioscientific value. At stake was the everyday sense of self: of being able to lead an ordinary, healthy and respectable life in conditions that have been rendered extremely precarious by centuries of domination, exclusion and racial stereotyping (Jensen 2008; F. Ross 2010).

In the introduction to this chapter, I suggested that the idiom of 'clean blood' not only danced to a different tune to vaccine trials but also potentially ran into tension with it. After the trial of MVA85A, there was a lot of talk about the susceptibilities of efficacy trials to 'failure' even when a vaccine shows promise in early-phase testing. One possibility, as suggested in Chapter 3 (p. 95), was that the intensity of case finding during the trial might have 'washed away' the effects of the vaccine before it had the chance to

work. This chapter suggests another possible interference in the trial design. Adult trials are powered by a 1.5/100 probability that a participant will develop TB each year. But what happens if people like Leighton are not passively accepting this disposition to sickness and, in the effort to set themselves *apart* as responsible, health-conscious individuals, start radically transforming their lifestyles? Could it reduce the number of TB cases below the number required to produce a statistically significant result? I am not advancing this suggestion as anything other than speculative conjecture of a social scientist and, moreover, do not wish to overstate the capacity of people's abilities to escape the structural determinants of TB. I only wish to underline that the so-called 'vulnerable' are not simply sitting down and awaiting their fate but rather using SATVI's trials in creative and unpredictable ways that have tangible effects both on their own lives and the trials themselves. Could it possibly be that the situated moral projects being pursued through the trials have weighed down and overtaken the biomedical future that the trials seek to bring about?

Most of these fascinating social dynamics, it might be noted, unfold beyond the visibilities of the state, among precisely the people and in the suburbs that the government clinics struggle to gain any control over (Chapter 4). While writing this chapter I could not help but wonder what Sister du Plessis will make of its findings, whether it will be met with interest, bemusement, scepticism or otherwise. In the next two chapters, I bring the government clinics back into the frame, and draw attention to the relationships, comparisons and connections between SATVI and these clinics. This is especially relevant given that many participants would be referred from SATVI to the clinics in the event they were found to have a medical condition. These chapters, too, highlight the tensions between the moral, respectable people that participants experienced themselves

as and the governmental stereotypes that resolutely lurked in the background (Jensen 2008).

## Chapter 7

### **“We are not Dominating Them”: Comparisons and Connections Between SATVI and the Government Clinics**

Moving back and forth between SATVI’s trial site and the government clinics during my fieldwork, one thing which never failed to strike me was the tangible difference in the mood and atmosphere between the two kinds of institution. Waiting for study visits, participants chatted, drank coffee, ate breakfast, watched TV, played music and manoeuvred chairs to sit in larger groups. They were also often social with the research staff, and it was not uncommon to see warm embraces between participants and staff, especially in the Adolescent Trial. By contrast, the government clinics were crowded, sombre and often tense environments. This was partially because more of those attending the government facilities were sick. But over this was layered the clear markers of state authority: metal detectors and security guards at the entrance (in the case of Worcester Community Day Centre [CDC]), people sitting quietly with their heads down and their body language closed, and people funnelled this way and that by uniformed nurses.

These differences were noticeable for me, but they also featured prominently in participants’ appraisals of SATVI’s research environment too. The previous chapter focused upon how people viewed their role in the trials and examined the complex interplay between personal and community health contained within the idiom of ‘clean blood’. Yet many participants – 59 (60%), in fact – said that among their reasons for taking part in the trial in the first place was a concern that they might have developed a medical condition they did not know about. This concern was usually most pronounced at the screening visit, where a variety of tests and examinations were conducted to



determine whether they were eligible to enrol (see Appendix 2); but as people were all-too aware, sickness and disease are ever-present threats in post-apartheid Worcester and could therefore occur at any point during the trial. SATVI's work consequently overlapped with that of the government clinics, and participation would directly lead to a visit to a clinic in the event that a disease was diagnosed and they had to be referred for treatment.<sup>30</sup> Building upon the previous chapter, this chapter explores how people concerned about their health perceived SATVI's role in the local healthcare landscape, especially how they drew comparisons and appropriated connections between SATVI and the government clinics.

I will argue that, while SATVI does not consider healthcare to be part of its remit, a combination of push factors from the government clinics and pull factors towards SATVI have led the institute to take on an important, albeit largely unacknowledged, role in the Breede Valley as a 'first point of care'. Part of the reason for this, I will suggest, is the superior medical resources and expertise that SATVI's trials have brought into the frame: shorter waiting times, high-end diagnostics, the presence of doctors and a referral process that might help to access healthcare through the government facilities (Barsdorf et al. 2010). However, perhaps the most important aspects of what made SATVI attractive to people as a healthcare setting had to do with the *relational* aspects of care.

Chapter 4 described how the Mandela administration radically restructured the health system to improve access to healthcare among those who had historically been most deprived. The Patient Rights Charter (1996) spelled out a range of rights, including those to a comprehensive range of healthcare services, privacy and confidentiality, participation in health decision-making and also to a disposition on the part of healthcare

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<sup>30</sup> As was discussed in Chapter 1 (p. 51), SATVI does not provide any treatment for any conditions diagnosed during vaccine trials but rather refers participants to their normal healthcare provider, usually a government clinic.

professionals that demonstrates “courtesy, human dignity, patience, empathy and tolerance”. Yet as the chapter went on to demonstrate, from the perspective of clinic staff there was a fundamental dissonance between the theory and reality of post-apartheid healthcare provision and it was difficult for them to always remain patient when, from their perspective, people often seemed unwilling to ‘take responsibility’ for their health. Participants, as this chapter suggests, viewed the situation very differently. They felt that in the government clinics they were unjustly subjected to scolding, feared that their medical information would become public and in general felt that they were on the bottom of a hierarchy that carries residues of the country’s past (Jewkes et al. 1998; Sokhela et al. 2013). Against this backdrop, the ‘flatter’, more dialogical health relationship introduced by SATVI’s trial environment was valued highly and, as I will argue, manifested in a powerful form of care. The respectful, dignified treatment people felt themselves to receive at SATVI represented the way that they felt entitled to be treated in the government clinics. And with few able to afford private medical aid or willing to shoulder out-of-pocket doctor expenses, participants made sure to use SATVI as far as they possibly could.

In making this argument, I draw upon the perspectives of both participants and research staff, especially nurses. However, by way of a clarification, this chapter privileges participants’ perspectives, both in order to highlight health-seeking practices, and also because their views diverged in certain respects from staff. Participants viewed themselves as responsible, health-seeking individuals using SATVI as a particular kind of health space. The research staff agreed with this to an extent and, as I introduced findings from participant interviews into my conversations with the clinical teams, they began to shed additional light on why participants saw the institute in this way. At the same time, many of the nurses experienced some internal conflict, wanting to see

participants in the light that participants saw themselves but also having to bear the consequences of when they demonstrated an apparent lack of concern for their health, much like the government nurses in Chapter 4. I leave these issues until Chapter 8, which explores the interactions between SATVI and government clinic nurse when it came to referring sick (and often ‘uncooperative’) patients to the clinics for TB treatment. This chapter, meanwhile, takes its lead from participant perspectives, gradually adding the perspectives of staff to shed additional light on why they perceived certain kinds of care in the research setting.

### **Perceptions of Care in Research Settings**

Social scientific studies have demonstrated in a wide variety of contexts that research relationships do not amount to the stripping away of care and that the organisation of clinical trials can engender unique therapeutic relationships. Easter et al. (2006), for instance, suggest from a study of early phase gene transfer trials in the US that participants, while aware that research was not being performed for their benefit, valued the relationship between the researchers and themselves more than their usual healthcare provider, especially because of the intimacy and trust that developed over time. Other studies focusing on research involving people with limited access to healthcare (e.g. uninsured citizens in the US, Russia and Poland) have further shown that participants receive not only treatment but also ongoing monitoring, psychosocial support and help in the case of emergencies (Fisher 2009; Petryna 2009; Timmermans & McKay 2009; Zvonareva et al. 2014). Stigmatised populations, as Timmermans and McKay (2009) suggest from their study on a trial involving methamphetamine addicts in the US, might derive particular benefit from trial environments, with non-judgemental staff, greater confidentiality than in the public sector, and also a supportive environment in which to attempt to break addiction.

Ethnographic and other qualitative studies in Africa have drawn attention to the stark difference between government healthcare and that which becomes available through participation in clinical trials (e.g. Geissler et al. 2008; Nguyen et al. 2007; Barsdorf et al. 2010; Nguyen 2011; Kamuya et al. 2014). However, perhaps because of this stark difference and the emphasis on the preservation of minimal survival, with notable exceptions (e.g. Barsdorf et al. 2010; Brives 2013; Zvonareva et al. 2014), emphasis has tended to be on biomedical interventions, considered outside of the healthcare relationships in which they are delivered (though fieldworkers have received considerable ethnographic attention [e.g. Geissler et al. 2008; Molyneux et al. 2013; Chapter 5]). In South Africa, there is evidence to suggest that this ought to be an area of focus, with several studies highlighting negative patient experiences in government facilities, for instance “rude” and “uncaring” staff, the public sharing of patient information and generally hostile and degrading environments (Jewkes et al. 1998; Muller 2004; Gilson et al. 2005; Sokhela et al. 2013). There is thus a gap in the literature focusing upon how participants in clinical trials perceive research relationships in relation to those in government facilities.

Barsdorf et al. (2010) note that in most preventative trials in South Africa, participants are referred to government facilities for treatment (as with SATVI). They argue that it is important to discern how people view the responsibilities of researchers in such arrangements given the under-resourcing of public programmes. Speaking to stakeholders in HIV prevention trials in KwaZulu-Natal, they show that the research relationships were perceived as “caring and supportive” (2010, p. 84) and that, because researchers were viewed as being in a relationship with participants and in position to do so, that they should help facilitate treatment through the public programs. Yet they offer little sense of the historical context of the clinical trials in the region, the social substance

of these ‘caring and supportive’ relationships and the extent to which perceptions of care were informed by experiences in government facilities.

In this chapter, I will suggest that participants’ perceptions of care in the research environment were intimately connected with experiences in government clinics and, in fact, SATVI was viewed as almost the diametric opposite of the clinics. Once again, the empirical schema running through this thesis – that is, the transition from *abject* to *object* to *subject* (Sariola & Simpson 2013) – is useful for shedding light on why participants viewed the research environment so positively. Accustomed to scolding, disciplining and other indignities in the government clinics, people felt highly vulnerable and exposed when seeking healthcare through the public sector. Yet their disposition to develop TB made them valuable as scientific objects, placing them in the line of sight of SATVI’s TB vaccine trials. In the process of becoming objects, they were “reconfigured as universal ‘human subjects’” (2013, p. 52), that is, autonomous, rights-bearing individuals “to whom certain standards, protocols and guidelines apply” (ibid, p. 52). Much of what it means to be treated as a universal human subject, for instance as autonomous and with dignity and respect, might barely register in a Western research setting. However, when viewed against the backdrop of the post-apartheid health system, the novelty of SATVI’s research environment to participants becomes more apparent, as does its positive uptake.

## **Health Checks and Blood Screenings**

When discussing the health-related benefits of trial participation in the previous chapter, the main focus was on blood tests and the close interconnections between personal and community health. But as I found during interviews, SATVI’s reputation as a health setting went beyond blood tests, and people were well-aware, often before a fieldworker had explained the trial procedures, of the broader ‘package’ of tests and examinations that were performed at screening and throughout the follow-up process (Appendix 2).

Knowledge of SATVI's diagnostic capabilities often came from having friends, children, relatives or others who had taken part and who have had positive experiences. One participant in the Adult Safety Trial explained to me that her child had been in the trial of MVA85A and her experiences led to her to take part herself:

JD: Can I ask, why did you choose to have your baby as part of the study?

R: *Soos julle mos nou weet, TB is 'n groot ding in die gemeenskap. En hoekom ek vir hom daar neergesit het, dis omdat ek stel belang in my kind se gesondheid.* (As you know, TB is a big thing in the community. And the reason for putting his name down, it's because I want to know about my child's health).

..... (a few minutes after)

JD: So did having your baby in the study make it more...did it affect your decision to take part in this study yourself?

R: Ja, ek het goed gevoel. *Dis hoekom ek nou maar self hiernatoe gekom het.* (Yes, I felt good. That's why I came here myself).

(23, F, A, ST)<sup>31</sup>

Memories of SATVI's work and what the trials entailed for participants went back as far as the BCG trial, it might be added (Chapter 3). But it was not only TB that people were worried they might have and that would be revealed through the trials procedures. In fact, HIV was mentioned just as often as TB. Worries about HIV were most pronounced in the HIV-Exposed Infant Trial, in which *all* of the mothers took part for the health of their babies (see Chapter 6, Table 2, p. 169) and were concerned in particular with ensuring that they did not pass on the disease to their babies. But in the other trials, too, participants

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<sup>31</sup> See Chapter 6, Table 1 (p. 164), for the guide to shorthand used to describe participant demographics.

mentioned HIV tests among their reasons for taking part:

JD: So can you just tell me a little bit about how you got involved with the study?

R: My friends were part of the study. I asked them how does one get involved. They told me, but I never really got a chance. But I kept on asking them when will the people be coming back to you again; when will they ask the people again. Because I'm very interested in becoming part of the study...

JD: What did you see your friends doing that made you want to take part? What made you interested?

R: They told me about the tests for TB that you get tested for, and AIDS.

(20, M, A, ST)

Aside from infectious diseases such as TB and HIV, people also mentioned chronic diseases such as hypertension, diabetes and high cholesterol. Many did not have any particular worry in mind when consenting to take part but simply wanted to receive a thorough medical examination. With people seemingly using SATVI in a similar way to how one might use any other healthcare provider, I then asked participants why they wanted to hear about their health at SATVI rather than elsewhere. This question, I found, hit a nerve. For it prompted many to speak passionately about the differences between SATVI and the government clinics as well as the connections between them. The rest of the chapter is divided into four sections, reflecting the main themes that emerged from participants' reflections: access and clinic environments; hierarchy and communication; diagnostics and follow-up; and referral into the health system.

### **Access and Clinic Environments**

Most of the participants I talked to live in Worcester, either south of Durban Street or in

the township of Zwelethemba. With Worcester CDC sitting just north of Roodewal, and Empilisweni clinic lying at the edge of the township, most residents lived near to a government clinic. There were notable exceptions, however. Residents living in Avian Park were located around eight kilometres from Worcester CDC and thus this often meant paying for a taxi to the clinic if necessary.<sup>32</sup> Moreover, those living on the farms outside of Worcester – which included several of the adolescents – either had to wait for a mobile clinic or get a lift with the farmer to town. Another, less visible barrier to accessing healthcare were the gang territories. When I was in Riverview with Jenna, one of the nurses, we encountered one incredibly thin young woman who had TB disease but who had stopped attending the clinic for medication. Looking like she was near death, Jenna asked her why she did not seek treatment when the Worcester CDC was only ten minutes away on foot. Her boyfriend was a gangster, she explained, and going to the clinic meant going through Roodewal, a rival territory, where she feared she would be recognised and shot. Sadly, it appeared that allowing her physical health to deteriorate was the more promising alternative.

Most participants could make it to a government clinic without too much difficulty. In fact, there is such thing as being *too* close to a clinic, as will be discussed shortly. One of the first, although by no means the least appealing, aspects of the government clinics that people related to me was just how long the queues could be (Bogart et al. 2013; Sokhela et al. 2013). Queuing occupied the vast majority of the time spent in a public clinic, especially if one had not yet been diagnosed. This meant starting a clinic file (if necessary), going through observations and seeing the primary healthcare sisters before being moved onto a more specific department (if necessary) – each of which had its own

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<sup>32</sup> Given the lack of access to a clinic in Avian Park, which had among the highest rates of infectious disease, the district manager Dr Van Zyl informed me there were plans to build a clinic there in the coming years.



queue. One young lady, speaking of Empilisweni clinic, said that: “Their service is not good at all, because if you go there at eight o’clock in the morning, maybe you are going home at...The whole day you were there” (21, F, X, ET). By contrast, SATVI’s trials allowed one to avoid this queueing process to an extent:

JD: Would you rather hear about your health here than anywhere else?

R: Yes.

JD: And why is that exactly?

R: Because when you go to the day hospital or something, then you have to sit a long time. You don’t get the results easily, like they get it here. Then you have to wait a long time. But here it’s very quick. You get the results quickly.

(44, F, A, ST)

People related a similar situation in relation to the recently established appointment system at Worcester CDC and De Doorns clinic. This system was designed to manage the flow of patient traffic more efficiently, and involved people making an appointment, either in person or over the phone, to be seen during a specific hour window on a given day. While the impression that I got from the clinics was that this would mean waiting a few days at most, a number of participants expressed that it could take several weeks to get an appointment, especially if it was deemed not to be urgent. Their impression, therefore, was that the new system functioned to further limit access to state resources, keeping the problems beyond their walls (Muller 2004). SATVI, again, was perceived to offer faster test results: “I just wanted to find out if I was HIV-positive, and that lady [SATVI nurse] told me she’s going to do it right now because at the clinic you can wait two or three weeks...And I got my results” (26, M, A, ET).

It was not just the length of waiting times, however, that set SATVI apart from the

public clinics; it was also the kind of waiting environment. Muller (2004), in an ethnographic study of a community health centre in the Cape Flats, noted that the building became “increasingly fortified” in response to gang related activity in which clinic staff had been threatened and injured. Worcester CDC had a similarly fortified appearance and security presence, given its proximity to gang territories, and a number of participants expressed how cold the building felt. SATVI, by contrast, had a much warmer and friendlier feel to it, and participants were often quite taken aback the first time they came.

They took our names and came to explain what the study was about. I read the pamphlet that they gave me. Then they contacted me to say when they were going to fetch me. But I find it quite...how can I say...the people who are working here are very friendly, even the cleaners and the girl at security, they are also very friendly.

(40, F, A, ET)

People also commented on the food and coffee that they were offered while waiting: “It is nice, because they are offering us coffees with biscuit” (21, F, X, ET); “So at least *apha uyakwazi ukufika utye. Kumnandi wethu* (So at least here you can arrive and eat. It’s just nice” (20, F, X, ET). This perceived kindness and conviviality also characterised appointments, which will be discussed below.

Arguably the more pertinent aspect of the waiting environment at SATVI for those who were concerned about their health, however, was the inscrutability of people’s health statuses. At the government clinics, the queues were not only long; people would also end up waiting outside of the department – for instance prenatal, infectious disease (primarily HIV), TB, and chronic disease – that they would be visiting. People were absolutely *terrified* that other people would see them waiting and make assumptions about what diseases they had. This was especially pertinent among Xhosa-speaking participants,

given the proximity of Empilisweni clinic to the community that it serves and the modest size of Zwelethemba. One young woman said: “At the clinic there are a lot of people...And they’ll know your status, and they will go around and talk about it” (23, F, X, ST). Another said: “Like now, they said, if you’re sick with this sit here; if you’re sick with that sit there. So people know, if you’re there, oh you have a problem” (21, F, X, ET). I even heard that often people in Zwelethemba would use Worcester CDC rather than Empilisweni clinic, especially regarding HIV, in order to receive medical attention. These findings are by no means unique in South African contexts (Horwood et al. 2010; Gilbert & Walker 2010) and, moreover, Abney (2011) found that TB patients sometimes commute to avoid being seen at their local clinic – such was the fear of stigma

At SATVI, by contrast, it was far more difficult for people to know who was there for what reason, or whether they were healthy or whether they were not. The one thing that might be suspected of a participant, as discussed in the Chapter 5, was that they were there for the R150 ‘reimbursements’. This was an image people were concerned with avoiding, but certainly less so than a having stigmatised disease (i.e. TB or HIV).

## **Hierarchy and Communication**

After waiting for a short while, participants were almost invariably greeted by a warm, smiling nurse as they went in for their appointments. In the last chapter, I described the social dynamics of nurse-participant interactions, but without a comparative focus with government clinic nursing. That there might be a discernible difference between SATVI and the government nurses was recognised right from the BCG trial. SATVI’s first site manager Dennis – who we heard much from in Chapter 2 – attributed this to the very different settings within which the nurses were engaging with people:

The BCG [SATVI] nurses are so kind, and the public service nurses are so

rude. They say “wait there” while the BCG nurses say hello, call you Mr or Mrs, and ask you nicely...Those sorts of thing [attitudes of clinic nurses] are real, this patient for the public service nurses is one of a thousand, and for the BCG nurses this is one piece of gold, one that you must have.

Dennis was referring to the overcrowded, rushed and irritable environment of the government clinics, in which each patient is but one many who need to be manoeuvred through the crowded clinic spaces, often through the use of commands. By contrast, the power dynamic is inverted in the research environment, with each individual carrying a far greater “value”, which necessitates individualised, friendly treatment: *asking* them not *commanding*. Based on the previous chapter, I would contest Dennis’ characterisation of participants’ value to the nurses in terms of a “piece of gold”, a term which brings to mind the notion of “biocapital” (Sunder Rajan 2006). Nonetheless, there was certainly a retention motive at play during research interactions, to a greater extent than clinic ones.<sup>33</sup>

Lydia, a professional nurse during the BCG trial and now head of human resources, suggested that the way that participants were treated by research staff in comparison with the government facilities was often a “convincing factor” for participants:

They saw that as a convincing factor to participate in the research, because they get a good medical examination, and people are actually nice to them, and have time for them. Because the health services can be pretty offhand and you have to wait forever, and then you get to an irritated nurse. Whereas now

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<sup>33</sup> This is not to say no retention motive exists in the government clinics. Persuading patients to keep on their medication is certainly made easier when nurses strive to be friendly and respectful to patients. The difference is that in research encounters, even if a participant does not follow protocol, one can *never* rebuke them.

everyone is happy to see you...so you can hardly blame them for participating.

Lydia also, interestingly, mentioned that they don't judge the adolescents about having sex: "They [SATVI nurses] don't look down on the teens and say 'what the hell are you doing here', rather they say 'please, you need to have safe sex'". The implication that attitudes to the effect of "what the hell are you doing?" are prevalent among government nurses is supported by a number of studies (e.g. Wood & Jewkes 2006; Harries et al. 2009).

One professional nurse, Lorna, perhaps went the furthest in connecting the ways in which participants are treated at SATVI to the legacy of domination and control in the health sector from apartheid. For her, the fact that SATVI nurses did not wear uniforms went some way to relinquishing control and domination over them and emphasising that it was *their* choice whether to take part:

The fact that we don't wear uniforms, we wear private clothes, so we are not dominating them. We respecting their rights as a person. So, if I had my epaulettes on, they know if I speak they must just do. But here, you give them an open platform to say yes or no. You're not enforcing. You're not forcing them to take part.

Lorna's statement adds to the findings presented in previous chapters. Chapter 5 explored the recruitment practices of the fieldworkers and showed how they attempted to 'lower' themselves to mitigate the difference in socioeconomic status between themselves and participants, from which they attempted to make people feel valued. Chapter 6 demonstrated how the study nurses strove to look beyond the distanced, objectifying logic of trial protocols to acknowledge the people sitting in front of them. Lorna's assertions suggest that we add the visible identity of research nurses as "private" citizens rather than

as state actors as another key way in which the research relationship relinquishes of power and control over participants in favour of more equal engagements.

Participants had very much the same opinion, and their explanations are consistent with findings from studies offering patient perceptions of government clinics (Jewkes et al. 1998; Gilson et al. 2005; Goudge & Gilson 2005; Sokhela et al. 2013). To give a sense of just how pertinent the stark difference between SATVI and the government clinics was to participants, in one of my first interviews I was in the middle of asking my first question when the woman in front of me cut in:

R: *Kan ek gou net iets sê?* (Can I just say something)?

JD: Hmm.

R: *SATVI is vir my beter as die klinieke, want as ons kliniek toe gaan met 'n probleem, ek voel nie lekker nie of as ek nou gaan vir 'n toets, hulle verwys...hulle sê vir jou maak 'n datum, maar hulle help jou nie baie lekker nie.* (SATVI for me is better than the clinics because if you go to the clinic with a problem, maybe I'm not feeling well or I'm just going for a test, they refer...they tell you to set a date, but they don't help you very nicely). *Hulle gesles nie lekker met jou nie.* (They don't talk very nicely to you). *So die klinieke hier rond, dis maar nou net hoe ek voel daaroor, hulle diens is baie swak.* (So the clinics around here, that's just how I feel about it, their service is very poor).

(24, F, A, ST)

Many other participants related the way in which they were treated in the government clinics, although I will relate just two more examples here:

They're going to shout you; you don't come, you don't come eat your

medication! All that stuff, blah, blah, blah.

(21 F, X, ET)

*Daai* Dr [actually referring to a nurse at Rawsonville clinic]...*ek weet ook nie wat is haar naam nie...sy is baie onbeskof.* (That Dr [nurse], I don't know what's her name...she's very rude).

(14, F, A)

What was troubling to me upon hearing these accounts from participants was that it was not only patients who had given the government nurses a reason to reprimand them, such as being 'non-compliant', who were treated as such (which is problematic enough in itself). It seemed also that there was a presumption in advance that all patients were like those who had been before them. This might partially be due to the busy and irritable atmosphere of the clinics, with the nurse already in a bad mood. But it seemed to be more than this; people felt that a stereotypical frame was placed over them, which at Worcester CDC might be called "problematic colouredness" (Jensen 2008, p. 183). This was partially suggested in Chapter 4 by Sister du Plessis' frustrated statement, "You can't be nice to them. If you give them the pinkie [little finger] then they will take the whole hand". The result was that people felt that they were already on the defensive when they stepped foot in a clinic, ready to be placed in the role of the unruly patient. It might be supposed that this presumption, in turn, could feed into a self-fulfilling prophecy in some cases.

An important and closely-related aspect of trial interactions to the above discussion of hierarchy and power is that of *communication*. Clear communication between researchers and participants, as well as giving participants the opportunity to ask questions, lie very close to the heart of research ethics, because it is integral to people making rational, informed choices to take part in clinical trials (Andanda 2005; Geissler et al. 2008). Trial protocols dictated that at every visit, participants were informed of what

was happening, asked whether they were happy to continue taking part (i.e. not just during the initial consent process) and given the opportunity to ask questions. Of course, one of the most important messages to be communicated was that the trial was being conducted for the purposes of knowledge production and not for the benefit of participating individuals. Yet, the open channels of communication between SATVI's staff and participants – the freedom to ask, question, be critical and hold staff to account – was part of what made SATVI attractive as a health setting. This was related by both staff and participants, often closely interrelated with the theme of hierarchy. Study co-ordinator Dayna, for example, said:

People are more open about discussing their health here, and their problems, and their treatment, or their participation in the study. People aren't scared to ask what their results are, for any test SATVI do. In the clinic, they're scared that the sister is going to shout at them, or be very short with them. Here, on the other hand, we are very open with participants. We make it clear that they can complain if there's something wrong, and that they make staff feel accountable. This makes them open up to you.

Examples from participants were again numerous. Many spoke passionately about how they valued how they had everything clearly explained to them at SATVI, contrasting this with the way 'care' works in the government clinics:

JD: Why would that be? What do you consider to be nicer about hearing it here?

R: At the clinic the people aren't really friendly. They would just talk to you like that. But here they are very friendly and they will explain to you nicely, step-by-step, how everything works and how you can get it and so on.



R2: What is the difference between the service at the clinic and the service at SATVI? What can you say is the difference?

R: Like I've said, they are friendly. We won't still say, no, we're not coming back tomorrow when they're calling us. But at the clinic they will maybe say, no, we're not going to come again because there isn't a good service.

(32, F, A, ET)

JD: What do you expect them to do if they find out there's a problem with you?

R: In the time that I'm here and they maybe find out that there's a problem with me, then I would prefer that SATVI's doctor refers me and then I will go to a private doctor on my own. But I don't have a desire to go to GGS [Worcester CDC], you understand. Okay, sometimes there are doctors who you feel safe to talk to, but at other times there are sisters who just...how can I say...look, here at SATVI, you feel free to talk and to ask questions, but there you don't feel...because you don't know...I can ask the sister a question and she will explain it to me, and then the other sister comes in and this one just starts to unpack...and some of them are very impatient and rude. They don't appear to be willing to help you. Then they will just tell you, go over to \*\*, or they will refer you to somewhere else. Very often they are impatient with you.

(33, F, A, ET)

Conducting research on patient experiences of public clinics in the eThekweni district of South Africa, Sokhela and colleagues (2013) found that patients could accept the inevitability of long queues in the clinics on the condition that they were treated respectfully and kept informed and 'in the loop'. Paraphrasing Leebov (2009), they argue

that “communication by nurses has the greatest impact on how patients evaluate their experiences” (Sokhela et al. 2013, p. 7; see also Walker & Gilson 2004; Gilson et al. 2005). This says much about the kind of care that people would like to receive in the government clinics. The way in which people are asked to make decisions for themselves in research settings has been shown to result in tensions in some contexts, for instance in Sri Lanka (Sariola & Simpson 2011). However, in a context where people did not feel that they were deemed worthy of participating in their own health, the novelty of having everything explained to them and being asked to take part in decision-making was received warmly.

There was, however, also value placed on knowing when *not* to communicate. Above I suggested that one of the reasons that people feared the government clinics, especially Empilisweni, was the publicity of medical information. It was also felt that in the government clinics, the appointments themselves were not confidential. One woman explained to me how she felt that appointments occurred in Worcester CDC, comparing this with the confidentiality at SATVI:

You talk to the sister...there are two sisters...you talk to the one about what your problem is and why you are there. Now, at that moment I'm a patient. Then she talks to you about what the other sister said, and then she talks to according what's in my file, I can call it, and then she shares this with you. But here are other patients as well, do you understand, and they are just talking amongst each other about this patient. And I've heard about this many times, they talk amongst each other about the patient, yes, she's got this and that wrong with her. But here, I can talk to the doctor and he keeps it to himself. Do you understand, it's private. I'm sitting with him on my own.

(33, F, A, ET)

Understandably, this was also an important concern for the mothers in the HIV-Exposed Infant Trial, all of whom were HIV-positive: “*By die kliniek voel dit nie vir my dis veilig nie. Hier voel dit vir my dis veilig want wat ek sê of wat uitkom sal net hier bly.* (At the clinic, I don’t feel safe. I feel safe here because whatever I say or whatever comes out will just remain here) (F, A, HIV-EI). This participant’s use of ‘safety’, a term often used in relation to physical threats, is a powerful way of expressing how profoundly vulnerable and exposed people felt in the government clinics. SATVI’s trials, rather than something which people are vulnerable *to* as bioethical literature suggests (e.g. Kipnis 2001; Lott 2005; Horn 2007), might actually be one of the only places people felt truly safe, allowing them to avoid, if only partially, some of the perceived indignities of receiving ‘care’ from the state. Between the inscrutability of the waiting environment (see above) and the closed doors of study consultations, the privacy and confidentiality afforded by SATVI’s trials were amongst the most important reasons that residents highly valued the institute as a health setting.

## **Diagnostics and Follow-Up**

So far, this chapter has explored why it was that SATVI was viewed as a preferable space to check one’s health without taking into consideration the *kinds* of diagnostics that are conducted during SATVI’s trials. One reason for not addressing this earlier is that, as I will suggest, matters of medical resources and expertise were very difficult to disentangle from the issues of the relational aspects of care that have been discussed above. This came out very quickly during interviews with participants. There was a feeling among many that, if they went to a government clinic for medical attention, then they were likely to just be sent away with paracetamol or aspirin. The implication was that they were not cared about enough to warrant the kinds of thorough medical tests and examinations that were needed to determine that they were sick and needed treatment:

JD: Why don't you like going to the clinic? What are the good and the bad things that you have experienced there?

R: *Uya e-clinic, ukuba uyile, ufumana iPanado, ukuba uyile ufumana i-Disprin, so hayi suka!* (You go to the clinic, if you go, you get Panado [paracetamol], and if you go you get Disprin [aspirin], so no go away!).

(27, M, X, ET)

Another vividly expressed that you would see people who needed to be sent straight to hospital but, rather than calling an ambulance, were just given “pills”:

JD: So what do you think, you mentioned some of their kind of whatever, what do you think are one of the main problems with Empilisweni or the good things or the bad things about the clinic there?

R: There's a people that are so very, very, very ill, sickly, they come to Empilisweni, give you pills, another people they are falling down when they comes out in the gate.

JD: Hmm.

R: They must know to call an Ambulance. There is no Ambulance there.

(40, M, X, ET)

There was, therefore, a feeling of being brushed aside. SATVI, by contrast, was perceived as a space in which comprehensive diagnostics were performed, not only at screening – although this was the point at which people were generally most concerned about diseases that might be picked up – but also regularly throughout trials. This involved everything from simple observations (weight and blood pressure) to high-end diagnostics (e.g. blood tests for liver and kidney function) that would not routinely be performed in the government clinics, as well as guaranteed examinations by a medical doctor. Professional

nurse Lorna gave a sense of the array of tests and examinations:

They love to join SATVI, because they know that for the first day they're being paid, but for the second they're also doing all the tests and stuff – liver functions, full blood count, HIV...And a doctor's examination, they have to sit with them before they start on treatment. They do a full history as a part of this. Here we don't have a problem with people saying no. To get a blood test through the clinic, you need to have a very specific problem before they'll do that. In the adolescent study, for instance, they are not just doing the vaccine, but also a load of tests to see whether they are generally well. The difference between the SATVI participant and the non-SATVI person is that they know what's going on with their health. The other is not up to date – even the urine samples...they pick stuff up at an early stage and can be referred for treatment.

Participants mentioned many of the diagnostic services described by Lorna and more when they expressed the medical benefits of the trials. One participant, for example, said that if she were to visit a government clinic, she might only get to see a nurse, whereas at SATVI she would see a doctor. Thus, whereas at the clinic she might be quickly sent home again – as others suggested above – SATVI would be more thorough:

JD: Would you rather hear about your health here at SATVI than, say, at the clinic or the GGS40 or wherever you go? Would you rather hear about your health here?

R: Yes, for me, I feel more comfortable here...Here, it's a lot better for me and a lot safer. Because sometimes, the clinics out there, they don't do what they are doing here with you. Sometimes, there they only take \*\*[possibly:

‘tests’] that’s done already. Here, at least you see a doctor and you explain to him. He asks you questions. Sometimes, there you don’t see a doctor. You can only just see the sister. Then she says, okay, your blood pressure is fine, you can go home. But here you can see the doctor and you can talk to him and tell him how you’re feeling and so on. I feel more safe here, here at SATVI.<sup>34</sup>

(33, F, A, ET)

In addition to the medical expertise of doctors, participants also had much faith in the blood tests to identify any diseases: “They check your blood every time”, one man noted. Indeed, in the previous chapter, following Carsten (2013a), I characterised blood as the “stuff of truth”, the tests sensitive enough to offer a window into their lifestyles beyond the confines of the trials. Between the availability of doctors and the sensitivity of the blood tests, there was therefore a far greater confidence in the diagnostic competency of SATVI, in contrast to the feeling that the government clinics might just send them away.

Some people would have a medical condition diagnosed at screening and were therefore referred to their local clinic for treatment (see next section). But for those who were enrolled into the trials, people also drew attention to the fact that they would be continuously monitored throughout the trials for signs of TB and other diseases (Zvonareva et al. 2014). As we saw in the previous chapter, this was not a passive exercise in waiting for the inevitable (cf. F. Ross 2010 Chapter 7), and in fact, as we saw, the monitoring process was used in creative and unexpected ways. Nonetheless, participants derived great comfort knowing that, *if* they developed TB or another disease during the study, then SATVI would soon tell them about it. Through the government facilities, by

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<sup>34</sup> Again, this notion of feeling “safe” at SATVI appears in people’s narratives, contrasting the institute with how they felt in the government facilities.

contrast, they were worried that disease would not be picked up nearly as quickly:

What I've realised is that if you are in this study and you get TB during this time, then it can be picked up easily and you can be helped. So your TB can be cured and you will receive any medical care for it. So for me this is a wonderful opportunity, and even for the community of Worcester and the towns surrounding Worcester, we are given a great opportunity from SATVI. So this is what SATVI put in. I'm also a community person and I would like to give. I've also studied home-based care. That is my field actually, but now...

(40, F, A, ET)

JD: So do you feel safer from TB, now that you are a part of the study?

R: I feel much safer.

JD: Why is that exactly? Now that you are part of the study, what do you think SATVI will help with?

R: You see, if I get TB now, I know that SATVI will tell me. But if I go to the hospital or to a doctor, they will just tell me there's nothing wrong, you've only got bronchitis or something like that. Then by the time they find out I've got TB, then the TB would have gone to the next level. You see, that's why.

(34, F, A, ST)

There really was some truth to this, as I will suggest in the next chapter. Of course, the follow-up process was directed towards proving the efficacy of a new TB vaccine as much as it was for the health of participants. In fact, as was noted in the description of the trial protocol above, there was a sense in which TB cases were actually desired (in the control group), for without these diagnoses a vaccine's efficacy cannot be proven. Nonetheless,

the fact that participants were regularly monitored for signs of disease was taken by many participants as a demonstration of just how much they *cared*. One participant, suggesting that there was “no care” in the clinics, said of SATVI:

JD: Did you decide it was better for your child to hear about his/her health here at SATVI than at the clinic?

RF: Ewe. (Yes).

JD: Okay, why is that?

RF: *Ingxaki iclinic yethu ayina hoyo kakhulu mandivele ndithethe nje nyani.*

*So ndabona apha ukuba umntu uhoye likhona. Nalanto ixesha elinzi uyafowunelwa ubuzwe ukuba umntwana unjani.* (The problem our clinic has no care, let me just tell the truth. So, I noticed that here for a person there is care. Even that thing for a long time you receive a call and you are asked how is the child).

(F, X, HIV-EI)

## Referral into the Health System

In the event that a medical condition was diagnosed during a vaccine trial, participants were referred to their local clinic for further diagnostics and potential treatment. Depending on the nature of the vaccine trial and its requirements, this might or might not have entailed exclusion (certainly a diagnosis of active TB would entail exclusion). Participants were, with one or two exceptions, well aware that SATVI's capacity to help them was limited to diagnostics and referral. Some suggested that they had *no* expectations of SATVI after the moment of referral: “*Hulle sal vir my sê ek moet kliniek toe gaan. En ek sal mos nou dadelik gaan want ek het mos nou by hulle uitgevind* (They will tell me when to go to the clinic. And I will go immediately because I found out from



them) (24, F, A, ST). Others, as Barsdorf et al. (2010) found in KwaZulu-Natal, said that they thought that SATVI should help them to secure treatment at their clinic:

JD: If SATVI were to find out that there's something wrong with your health, what would you expect them to do?

R: They must help me. They must say to me, right, we see that this is wrong, and we are going to help you and phone these people. So if that person comes with a problem, then they must be keen to help. So they will make it easier for me because SATVI will phone those people and those people will know about me, I can get an appointment and go to them. I can go on such and such a day and they will help me.

(44, M, A, ET)

People therefore did not see SATVI as a *replacement* for the government clinics, with SATVI taking responsibility for their health from the moment they entered a vaccine trial. 'Therapeutic misconception' would therefore be a very misguided characterisation of the way in which SATVI featured as a health space (Geissler et al. 2008; Kelly 2011; Leach & Fairhead 2011). Rather, SATVI was being appropriated as a 'first point of care' of sorts to potentially *avoid* some of the more deplorable factors that people associated with accessing care in the government clinics.

The referral letters take on particular significance when we take into consideration the fact that people felt that they would likely be turned away from the clinics with only paracetamol or aspirin after only trivial examinations had been conducted. Whyte (2011), based on her work in Uganda, draws attention to the materiality of paper in medical research and the ways in which it acts as a "material token" for access to healthcare. Referral letters from SATVI, bearing definitive test results alongside the institute's insignia and the signature of a researcher, were unsurprisingly viewed by participants as

legitimizing claims to healthcare that might otherwise be denied to them. I reserve a more detailed exploration of the mechanisms of referral until the next chapter, where we will see that participants' expectations that SATVI could help them enter the health system were not unfounded. However, at the same time we will see perspectives from both SATVI and government clinic nurses that depart from the self-imaginings of participants as responsible, health-seeking individuals. Suffice it is to say at this point that SATVI has rerouted pathways to care into a health system experienced as inhospitable and degrading.

## Conclusion

The expanding body of social science literature on clinical trials demonstrates convincingly that the orientation of medical research towards the production of knowledge does not amount to the stripping away of care and that, to the contrary, research can engender novel possibilities for care that are preferential in certain respects to accessing healthcare in 'normal' healthcare settings (Fisher 2009; Petryna 2009; Timmermans & McKay 2009; Zvonareva et al. 2014). The appeal of research participation is, understandably, heightened in contexts where government healthcare provision is severely compromised, as it is in the majority of African nations (Geissler et al. 2008; Nguyen et al. 2007; Barsdorf et al. 2010; Nguyen 2011; Kamuya et al. 2014).

In this chapter, I have contributed to this literature by drawing attention to the comparisons and connections that participants drew between SATVI and the government clinics. Various factors made SATVI attractive as a health setting, including shorter waiting times, high-end diagnostics, the presence of doctors and facilitated healthcare. But as I hope to have shown, the most important reasons that participants preferred SATVI as a health setting had to do with the *relational* dimensions of care – that participants felt valued, respected, included in medical decision-making and generally treated as equals. It must be noted that dignity, respect and inclusion are clearly

underscored into the Patient Rights Charter (1996), a document which is meant to engender a clean break from the exclusions and inequities of the apartheid health system (see Chapter 4). Yet, the reality today for the majority who are reliant upon the state for healthcare is a health service that is experienced as inhospitable, authoritarian and often degrading. In the fervent critique of neoliberalism in healthcare, it is rare to hear notions such as ‘choice’ and ‘autonomy’ being associated with care (Fisher 2007; Mol 2008). However, when SATVI’s trials are viewed against the backdrop of the post-apartheid health system – and the way in which people are reconfigured from objects into ‘universal’ human subjects (Sariola & Simpson 2013) – it is perhaps unsurprising that such notions might carry some appeal. Indeed, whilst SATVI considers itself to be outside of the health system, the practices and protocols that are designed to maintain this distance are part of the reason the institute is so deeply embedded within it, offering participants an approximation of the kind of treatment that they feel entitled to as citizens of post-apartheid South Africa.

The findings presented during this chapter, especially the reflections of participants, easily apportion blame to government nurses, casting them as rude, uncaring and authoritarian. One of the implied solutions to such attitudes is to retrain them in the ‘softer skills’ of patient management – which, it might be added, was beginning to happen during the year of my fieldwork. But an important reason why Chapter 4 focused upon the perspectives of nurses was to ward against easy solutions such as this. There, I argued that the nurses’ patient-blaming and practices of scolding were due to their having to manage a fundamental dissonance between the theory and reality of TB control, itself a function of a chronic lack of public spending on healthcare (Compion 2008). The fact that residents are clearly not as ‘irresponsible’ and ‘uncaring’ as their stereotype suggests does little to change the grievances of the government clinic staff. Rather, that government

clinic staff and the people they serve harbour such animosities towards one another testifies to the power of the neoliberal language of ‘patient responsibility’ to deflect attention away from structural determinants of both disease and under-resourced healthcare facilities. This chapter has shown how SATVI features in this unstable and divided healthcare landscape as a partial alternative to the government clinics. The next chapter, meanwhile, examines how the institute can appear from another angle as *part* of state governmentality.

## Chapter 8

### **“We Don’t Treat We Refer”: Sovereign Responsibility and the Transition from Participant to Patient**

“Next!” Upon hearing Nurse Jacob’s call, a skinny, bedraggled-looking man in his early thirties walked into the TB department of Empilisweni clinic. The man sat down, leant across the desk and handed Nurse Jacobs a letter. She took it, looked down and read it in a manner that suggested she had seen many like it before. It was a letter of referral from SATVI. Worded in polite language, the letter said that the man had been screened to participate in a vaccine trial but that the tests and examinations had revealed an abdominal abnormality which could be disseminated TB. The letter therefore advised that the clinic, as his healthcare provider, run further diagnostics.

Nurse Jacobs, looking up, was immediately cross with the man. This was because he had already been in the TB room with the same letter the previous week. Upon the recommendation of SATVI, they had booked him an abdominal scan at the hospital for yesterday – but he had not attended. Nurse Jacobs was cross not only because he had not turned up, but because it would be several days before he could have another done. She gave him a long, hard stare from across the table before saying to him sternly: “You were not here yesterday. I’m going to book you another appointment for Monday. Don’t forget”. He nodded and looked down. She picked up the phone and dialled.

While nurse Jacobs was on the phone, I had a brief conversation with the man from my position seated at the edge of the desk. His responses revealed experiences of trial participation that are similar to many of the other residents who appeared in the previous chapters. He told me that SATVI’s fieldworkers had visited his home, where he lived with his sister and her two children. Both he and his sister were interested in taking

part in the vaccine trial for which they were recruiting. After the fieldworkers had explained to them the inclusion and exclusion criteria, his sister was immediately deemed ineligible because she had high blood pressure. He, however, had not been diagnosed with anything – although, he expressed to me, he was not feeling well – and was booked in for a screening visit at SATVI’s site at the hospital a few days later. I asked him why he had decided to take part, and he cited a number of factors. He said that he was first and foremost worried about a pain in his chest and had gone to SATVI with the expectation that, as he put it simply, “they will help me”. Moreover, he said that “I want to donate blood”, quickly adding, “I like to donate blood for the people who need”.

Having found out at SATVI that he might not be healthy, he said that he was very concerned to get the problem resolved as soon as possible. However, he was not currently working. The reason that he did not attend the scan the previous day was that a potential job opportunity had arisen and he simply could not afford to pass it up. Therefore, he had attended the clinic first thing today instead. At the same time, he was in a bit of a hurry to get away again, as SATVI’s fieldworkers were due to return to his house today to give him the results of the additional blood tests they had run as part of screening. He was, it seemed, still hopeful that he could participate in the study. Yet of course, he would also need to show them the results of the scan. Knowing that I was working with SATVI, the man asked me in a worried tone, “what must I tell them [SATVI]?” At this point, Nurse Jacobs had gotten off the phone and heard the last part of our exchange. She was suddenly even more cross with him. After having words with the man, she turned to me and exclaimed, “you see, *now* he’s in a hurry because SATVI are going to *pay* him!”

This final ethnographic chapter completes our exploration of SATVI’s vaccine trials by focusing upon what occurred in the frequent event that a participant was diagnosed with TB or another medical condition, which could happen almost anytime

between screening and end of study visit years later. SATVI, as observed earlier, does not provide any treatment for diagnosed conditions during vaccine trials (cf. Geissler et al. 2008; Leach & Fairhead 2011). Rather, as is common in South African research contexts, where government healthcare provision is comparatively strong in relation to other parts of Africa, SATVI refers participants onwards for treatment, usually to their local government clinic (Barsdorf et al. 2010). The act of referral can be read as a status transition from ‘participant’ to ‘patient’, visibly enacting the differential responsibilities of research institutes and government healthcare providers. This not only upholds the sovereignty of the government in providing care for its citizens but moreover partially sidesteps the possibility of ‘therapeutic misconception’ that emerges when healthcare delivery more explicitly spills over into production of bioscientific knowledge.

The picture that I began to paint in the previous two chapters, however, was that despite the image of distance and objectivity, SATVI has become intricately entwined in the local context of health seeking and delivery. Chapter 6, especially, highlighted that participants perceived the institute as a safe, respectful and caring environment in which to undergo routine diagnostics and, moreover, a preferable point of entry into what was perceived to be a hostile and often degrading healthcare system. SATVI was, in fact, viewed as almost the diametric opposite of the government clinics, with its identity as separate from the state integral to its emergent healthcare role. This chapter examines SATVI’s effects on the landscape of primary healthcare from another angle and emerges with a different ‘version’ of its contributions. Focusing upon the institutional relationships between SATVI and the government clinics, the chapter asks: in what ways have SATVI’s trials stepped into the work of TB control? How did the government clinic staff perceive the flows of patients from SATVI to their doorsteps? How was responsibility for participant patients allocated and enacted? I draw upon the notion of

“sovereign responsibility” developed by Hannah Brown (2015) as a way of thinking through the complementarities, ambiguities and tensions that exist at the border between research and care.

I will show that SATVI’s research staff, especially nurses, were highly conscious of the institute’s superior resources and, as a result, in their communications with government clinics (both via referral letters and speaking directly), were conscious to display humility and deference to them as participants’ rightful healthcare providers. However, the institute’s incursions into everyday healthcare provision were difficult to ignore, in some cases challenging the sovereignty of the clinics, particularly by seemingly offering competing services and being seen to ‘pay’ their participants (as seen in the above vignette). Nonetheless, SATVI’s trials were, on the whole, valued by government clinic staff because they functioned to extend the state’s reach into hard-to-reach community settings via their mobility in low-income suburbs (see Chapter 5). Moreover, SATVI’s researchers were seen to actively survey participants during trials and place TB cases on the clinics’ radars when positive diagnoses were made. Responsibility for TB cases diagnosed by SATVI was ambiguous, however, especially in the event that participants did not promptly seek treatment and threatened to disappear from view. By showing how these responsibilities were worked out in practice, I suggest that the transition from participant to patient in the act of referral is a ‘bumpy’ one, leaving many grey areas for those who had to balance a sense of responsibility towards trial participants with the delicate relationship with the government clinics.

It might be noted that the ‘version’ of SATVI’s emergent role in healthcare presented in this chapter differs somewhat from that which emerged primarily from participants’ perspectives in Chapter 7. Whereas participants tended to view themselves as responsible, health-seeking citizens, this version involves a greater scepticism among



both research and clinic staff that participants always acted in the best interests of their health, especially when it came to a diagnosis of active TB. In fact, the governmental stereotype of the ‘irresponsible’, ‘uncaring’ TB patient which we have encountered time and again was frequently activated and placed over sick individuals. This chapter therefore ends the ethnographic chapters on a sobering note, reminding us of the limits of people’s abilities to cast off the structural violence that shapes them and underscores the magnitude of the challenges facing the health system in post-apartheid South Africa. I will not try to suggest that either the account presented here or in Chapter 7 is ‘correct’ or closer to the ‘truth’. Rather, I contend that these diverging accounts show just how messy and divisive the TB epidemic is and how complex research institutes’ entanglements in healthcare can be, lending themselves to multiple and conflicting interpretations.

### **Partnerships with Healthcare Facilities**

When clinical trials are conducted in resource-poor settings, substantial investments are often needed to support not only research centres but also government facilities involved in research. The superior resources that arrive on the back of trials are thus often highly visible and rendered side-by-side with normal healthcare provision. Despite the significant differentials in power and resources between research institutes/sponsors and host-country healthcare facilities, the relationships between them are, as Geissler (2013, p. 17) observes, framed within the language of collaborative partnership: “The language of collaborative partnership, compounded by the fictions of official government policy and those of the global development partners, insists that these different medical institutions and the clinical practitioners inhabiting them engage as equals”. The resources that are channelled into government healthcare facilities are thus theoretically regarded neutrally—or, if anything, as a “mere complement” to existing services (ibid, p.

22). The ethical framing of the relationships between medical research institutes and government facilities is thus very similar in kind to that between researchers and participants, that is, premised upon the ideals of autonomy and material independence (ibid, p. 18).

Based on ethnographic research with a team of district health managers in Kenya, Hannah Brown (2015) challenges the notion of equal partnership in global health. The multiple international NCGs that funded treatment programmes in the region were, theoretically, at the service of the state – they “‘supported’ programmes that the Kenyan government ‘implemented’” (2015, p. 342). Such relationships were often talked-up by the NGO representatives themselves as they sought to solidify their positions. However, in practice these relationships were more complex, because the NGOs had a vested interest in demonstrating the success of programmes. While the diverging imperatives and jurisdictions “were at times complementary”, these distributed and ambiguous jurisdictions often the resulted in “struggles over sovereignty” as NGOs and the managers asserted their managerial rights over health programs (ibid, p. 341). Brown calls the space in which the transfer of resources from sovereign to citizen are organised one of “sovereign responsibility” (ibid, p. 340). Under-researched in anthropology, this conceptual space is useful for shedding light on the pluralistic forms of governance that characterise neoliberal Africa and the workings of global health partnerships.

Complementarities and contestations in sovereign responsibility are implicit in a number of studies that have focused upon how clinical trials impact upon routine healthcare provision when they are conducted within government facilities. One of the main ways in which trials have been shown to be experienced positively by facility staff is through various ‘secondary benefits’ that accrue from trial-related activity. That is, benefits not due to the experimental interventions themselves but rather the operational

conduct of the trials. This includes things like improved service delivery, training for healthcare staff, additional transport services, and healthcare infrastructure (Sariola & Simpson forthcoming; Petty & Heimer 2011; Crane 2013; Geissler 2013; Liheluka et al. 2013; Tinto et al. 2014; Angwenyi et al. 2015). At the same time, however, clinical trials have also been seen to overstep their remit, with detrimental effects on healthcare. For instance, they can result in differential access to services for patients, siphon off staff, interrupt healthcare delivery and bring about uncertainty as to what will happen when the trials end (Angweni et al. 2015). Given the severe underfunding of government healthcare in many trial locations, the resources that arrive on the back of clinical trials are usually appreciated more than they are resented. Nonetheless, positive perceptions no less than negative ones question the ideals of ‘collaborative partnership’ and should arguably be viewed with a critical eye to obligations and expectations generated in unequal encounters.

Understandably, studies of government staff perceptions of clinical trials have tended to focus upon research conducted *within* healthcare facilities – on “how research reshapes clinics”, as Petty and Heimer (2011) put it. As observed above, however, in South Africa it is common during preventative trials for research institutes to refer all diagnosed cases to government facilities for treatment. Barsdorf et al. (2010), in one of the only studies to date with a focus upon such systems, show that participants and facility staff thought that researchers have some form of obligation to participants beyond the moment of diagnosis and should, for instance, “help participants to access” treatment. Yet, this says little about the relationships between research institutes and government facilities that are attendant upon the process of referral, especially in the context of a disease as challenging and divisive as TB. In the following exploration, I will further Brown’s (2015) notion of sovereign responsibility by shedding light on how

responsibility is allocated, managed and transferred between SATVI and government clinics. Importantly, we will see that while SATVI and the clinics were in almost absolute agreement as to who was responsible for what, the key dynamic throwing up questions of responsibility was the seeming unwillingness of people to act in the best interests of their own health and that of others (see Chapter 3). I thereby further Brown's analysis by showing that questions of sovereign responsibility can emerge not only because of competing interests between state and non-state institutions but because the subjects of research and care do not always follow the 'script'.

### **Refer not Treat, Advise not Prescribe**

In Chapter 5, we saw how SATVI's nurses, within a different kind of relationship with participants than in 'normal' healthcare settings, treated them as autonomous, responsible, health-conscious and community-minded individuals. This way of being treated, which was a novelty to many participants, was one of the most important reasons why they saw SATVI as a safe, caring environment in which to have their health checked and a preferable point of entry into the health system were anything diagnosed. However, several research nurses did harbour the worry that, with them being so 'nice' to participants, in conjunction with the other 'luxuries' of the research environment (e.g. transport, food, money), some participants would be more reluctant to trade this for their local government clinic when a diagnosis of TB or another medical condition was made. In this regard, the common expression, "we can't treat we must refer", was not only uttered with resentment of their limited capacity to help; it was also a reminder to participants and indeed themselves that, if a medical condition was diagnosed, participants had to be able to seek out treatment by themselves. Study co-ordinator Monique, for instance, said: "you need to refer them or make them responsible for taking this further, that's all you can do...we're very careful about not carrying the participant

– don't give them too much".

Referrals took the form of a letter bearing SATVI's insignia and address at the top. For ease of use, a template was usually typed up in advance of any given study, and all the author had to do was fill in the gaps with necessary details (Figure 13). The responsibility for referring a participant ultimately fell to the principal investigator. However, exactly who composed the letter depended upon the nature of the trial and the specifics of the diagnosed condition. In infant trials, for instance, it might be the principal investigator who examined information from the field and decided if they should be brought in for diagnostics, but from the moment they arrived, Brewelskloof Hospital's paediatrician Dr Gilbert took charge. Upon examination, he would either discharge infants or refer them using a SATVI-branded referral letter. In particularly severe cases, they might be admitted straight to Brewelskloof Hospital. In SATVI's adolescent and adult trials, where the hospital's doctors were not involved, it still did not have to be the principal investigator who composed the letter. Instead, it could be delegated to the study co-ordinator or a professional nurse (but never enrolled nurses or fieldworkers). Generally, one copy of the referral letter was handed to the participant to take to their local clinic and another was faxed through to their local clinic. But because of the infectious nature of TB, when participants were diagnosed, a case notification was also faxed through to the Department of Health.



**Figure 13: Typical SATVI Referral Letter**

Despite the international medical resources and expertise at SATVI's disposal, the referral arrangement was such that the moment participants were referred to the clinics, the state's protocols had complete authority – and referral letters were designed to reflect this deference. A primary marker of respect, I was informed, was that upon diagnosing a medical condition, the referral letter should *advise* not *prescribe* what should be done. As seen in Figure 13, the referral is generally phrased in the following way: “At screening/follow-up was found: ...[insert test results]... Please could you assess the participant, and refer him for further treatment, if necessary”. Humility was especially important when participants were sent having undergone tests that the clinics do not have the resources to conduct and that threatened to reveal a resource ‘gap’. Dayna explained

this to me using the example of the quantiFERON blood test for latent TB:

We can't force ourselves on the health service...Let's say a participant is quantiFERON positive...So we would write a referral letter to the clinic saying, "this participant is taking part in this study, one of the criteria was that we did the quantiFERON test, which came back positive. That is a marker for IPT [isoniazid preventative therapy]. Could we please advise you to work according to your programme?" So, we're not going to say, "you have to do the IPT [isoniazid prophylactic therapy]", rather "we advise you to work according to your IPT programme".<sup>35</sup>

Although deference to the authority of the state was written into trial protocols, I quickly found that SATVI's nurses, particularly those who had previously worked in government clinics, fully supported this stance towards the clinics. This was because they knew the hierarchical nature of the healthcare system and the respect that one was expected to show towards their superiors. Thus, they were aware how badly referrals could be received if they were perceived to challenge the authority of existing power structures. If anything, the notion of 'collaborative partnership' that tends to frame the relationships between research institutes and public facilities in the transnational research enterprise (Geissler 2013) conveys *too* much power to SATVI when it came to everyday interactions with the clinics. Monique, for example, expressed to me that whenever engaging the clinic staff, especially when visiting the clinics personally, one had to place oneself at the very bottom of the pecking order to receive their attention. As she put this, "you have to make yourself so small, smaller than the patient". It might be noted that this act of 'lowering' oneself

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<sup>35</sup> Isoniazid is one of the first-line drugs for the treatment of TB. However, it is also used as a preventative drug for young children who have been in contact with a TB patient. Isoniazid preventative therapy (IPT) is a six-month regimen, as with TB treatment.

was observed in Chapter 4, where the fieldworkers attempted to construct a meaningful environment for the consent process in the houses of Worcester's poorest.

What SATVI's staff had somewhat less control over was how their participants acted when they were referred to the government clinics. This also had the potential to challenge the sovereignty of the clinics in a similar way to how research staff acted. I was speaking to Anna, a research nurse who had worked at Worcester CDC during the BCG trial and recalled when participants first showed up on their radar:

Right in the beginning, the relationship wasn't so good. Some of them didn't introduce research so clearly to our people. Now they just hear there's blood that they draw, money and that. And now they come to the clinics and they tell us "we can't take this because we belong to SATVI" or "we can't have this injection because we're already at SATVI". Then you must tell them SATVI isn't a clinic, its only research. You must still come to our clinic...So it was *our* work, then, to go and sit and tell them you must still come to the clinic for your injections, your chronic medications. You are only taking part in a *study* of SATVI. They think they can leave us because they are with SATVI now.

Feelings on the part of participants of 'being with' research institutes have been observed in research contexts elsewhere in Africa, especially where routine healthcare is offered as part of trial participation (e.g. Geissler et al. 2008; Leach & Fairhead 2011). But this, as we can see, was considered an affront to the authority of the clinics given that SATVI were supposed to stay clear of this domain. The findings presented in Chapter 7 suggest that few participants today would consider SATVI to be a direct 'replacement' for the clinics. This is no doubt a result of considerable efforts on the part of SATVI's staff to convey to participants that they can only refer them and to defer to the sovereignty of the



clinics in this regard. Nonetheless, as we also saw in Chapter 7, and will see in this chapter from a different angle, SATVI's resources continue to exert considerable influence upon the local context of health seeking and delivery, particularly in relation to case finding and management, that no amount of deference, humility or distancing could entirely obscure.

### **Clinic Staff Perceptions of SATVI**

When spending time with the clinic nurses in Worcester Community Day Centre (Worcester CDC), Empilisweni and De Doorns (especially their TB rooms), I was interested in how they perceived SATVI's studies and how they affected their day-to-day work. I witnessed a few concrete examples – such as the vignette with which this chapter opened involving Nurse Jacobs – where participants came into the TB rooms bearing referral letters. But in fact, the nurses felt that the best way to give me a sense of SATVI's effects upon day-to-day healthcare, especially TB control, was to find examples of the patient folders of participants. These stood out because, for ease of identification, 'SATVI' was usually written in the top left hand corner. Moreover, often the first document inside – of which there could be many, including DOTS support documents, details of complications and non-adherence, and referrals to and from Brewelskloof Hospital – was the referral letter from SATVI that had brought them to the clinic the first place. Sister du Plessis estimated that, since she started her work with TB in 2009, approximately 10% of their caseload had come from SATVI, which reached a peak of around 20% during the latter stages of the large infant trial of the vaccine MVA85A between 2009 and 2012 (see Chapter 2). Given the nature of SATVI's trials since 2001, the majority of the participants referred to them were infants and, of these, a large proportion were not actually sick but required isoniazid preventative therapy because they had been in contact with a TB patient. Nonetheless, with an increasing number of

adolescent and adult trials being run, referrals from these age groups were common too.

Although my ties with SATVI might have influenced them somewhat, the nurses generally had positive views of research staff, suggesting that the value placed upon deference and humility – making themselves “so small”, as Monique put it – had its intended effect. Nurse Jacobs, for example, said:

They really try to be humble when they come in. And they wait for their chance to knock. Nobody behaved rudely that I know of, or don't want to wait. Because when they are coming in here they wait. They ask for something, and then we can't help them that morning. And they're not only bang in here.

They also did not see the referrals sent from SATVI as a burden upon them. For instance, I asked the facility manager of De Doorns clinic whether she considered SATVI's trials to give them “extra work”, to which she replied: “No, not really. In fact, I see that as our patient, and we need to render a service on a daily basis to that patient”. There was even a feeling that SATVI were more respectful when referring participants to the clinics than other referring institutions were (e.g. secondary hospitals), which were sometimes perceived as ‘dumping’ patients upon them: “They just say, go to the clinic, go to your nearest clinic, that's all they tell them”, as the TB clerk at Worcester CDC put it. In short, from what I could ascertain, there were no feelings among the nurses that I spent time with that SATVI's staff were ever rude or disrespectful when interacting with the clinic. Whether it was because their ‘insider’ knowledge of the clinic power structures or otherwise, they were generally well regarded and were not considered a burden upon routine healthcare.

But at the same time, SATVI was not regarded as a neutral, distanced actor, a mere ‘collaborator’ operating in the separate realm of research (Geissler 2013). Despite

conscious displays of deference by SATVI's staff, the clinic nurses were under no disillusion that SATVI had command over greater resources than they and which impacted upon the local context of health seeking and delivery. From their perspective, it was SATVI's high-resource environment that convinced people to join the trials, often as a partial alternative to the government clinics. Their reflections in this regard overlapped considerably with the findings presented in Chapter 7 (see also Barsdorf et al. 2011; Zvonareva et al. 2014). They mentioned the queueing: "They don't want to sit in line. People get very impatient to sit in the lines" (Nurse Jacobs, Empilisweni). They mentioned perceptions of rude and uncaring nurses: "The people, when you ask them, they will tell you that they have this picture of nurses, if they miss only one date, then the nurse won't help them" (Sister Harmse, De Doorns). They were also aware that people were terrified of the stigma associated with HIV and which SATVI somewhat allowed their participants to avoid. Nurse Jacobs said to me:

SATVI is more private. The people that are going into their houses, they don't need...as I say, there's a stigma if you go to room six. Then they know, oh, if you're sitting by room six, then you are HIV-positive. But if they're going into the houses they know, okay, they are busy doing a study on TB. There's a difference. If they're coming to the clinics, if you're going in by that room, you've got HIV.

Overall, however, they thought that monetary 'reimbursements' were the primary driver of participation in SATVI's vaccine trials: "they give money for them and it helps with their needs" (Nurse Jacobs, Empilisweni); "they get R150, and then they do tests" (Sister du Plessis, Worcester CDC); and "money, usually money, because my friend is doing that now" (Paediatric Nurse, Worcester CDC).

While the significance of the money appears on first glance to be socioeconomic,

interestingly I found that it could contest the sovereignty of the clinics no less than ‘alternative’ healthcare services. Firstly, the idea that SATVI were ‘paying’ their participants ran up against the way of thinking that the clinics strove to instil in Worcester’s constituents, that premised on ‘taking responsibility’ rather than incentive. This, as we saw in Chapter 4, had political inflections, with some nurses resenting that in post-apartheid South Africa people expected everything to be ‘handed’ to them, one of the reasons that the current model of healthcare relations does not function well. SATVI, therefore, sent the ‘wrong’ kind of message to the community they were trying to influence. Secondly, in terms of routine healthcare relations, when a participant entered a TB room bearing a referral letter, it could place a measure of doubt in nurses’ minds, as shown in the vignette with which this chapter opened involving Nurse Jacobs and her patient. Were they there out of genuine concern for their health or simply that they were afraid that, if they did not, they would lose out on their R150? “You see, now he is in a hurry because SATVI are going to pay him!”, was the nurse’s frustrated exclamation. In short, the shadow of SATVI always followed participants into the clinics. And any association with the institute had the potential to raise eyebrows as to what was motivating their appearances at the clinic and whether they would continue attending once the incentive was off the table.

Despite a degree of resentment and perhaps envy that SATVI had a greater ‘hold’ over the Breede Valley’s constituents than they, the clinic staff nonetheless thought that the trials made an important contribution to TB control. As I have begun to show already, this ‘version’ of SATVI’s healthcare role diverges from that which emerged in Chapter 6 and involves a heightened scepticism among both research and government clinic staff that all of their participants were concerned first and foremost about their health. The following exploration is split into two partially overlapping sections: (1) community

presence and active case finding; (2) post-diagnosis management of participant patients.

### **Community Presence and Active Case Finding**

In Chapter 4, I suggested that one of the main frustrations of the clinic nurses regarding TB control was that, despite the contributions of NGO-funded home-based carers, they felt unable to access and exert influence on Worcester's low-income suburbs, especially Riverview, Roodewal, Avian Park and Zwelethemba – the TB 'hotspots'. The feeling of confinement behind the walls of the clinics was felt particularly strongly by those nurses who had practiced during apartheid and where, although healthcare was highly inequitable (Packard 1989; Coovadia et al. 2009), for them it was a time of greater community presence and control. By contrast, SATVI was perceived to be an active presence in precisely these hard-to-reach areas. The facility manager of Empilisweni, for example, said to me that "they [SATVI] are not so much in the clinics. The place they are is mainly in the community". Sister Kruger of Worcester Community Day Centre similarly said: "I see a lot of cars driving around in the community, visiting houses". Nurse Jacobs, reflecting upon the poverty in which most TB patients live, commented that "they [SATVI] see the situation at the house and so on". SATVI's trials, in other words, led them to be an active presence in the areas that the clinic nurses wished they were able to exert greater influence.

But SATVI were not only active in these areas; the government clinic staff were also well aware that, once people had agreed to take part in a vaccine trial, they were screened for TB by the institute's nurses and doctors and then regularly followed up throughout to determine whether they developed the disease. "They follow up that patient very well", as Sister du Plessis explained. Although few of the clinic staff referred to it as such, what SATVI were effectively engaged in by screening and following up participants for TB was a form of active case finding. Active case finding is deemed the

appropriate standard of care for contemporary TB vaccine trials (Moyo et al. 2012), and involves actively searching for TB so that cases are picked up and picked up earlier, which gives participants a better prognosis. In fact, active case finding has recently been advocated by the WHO as a necessary component of TB control because, although passive case finding in conjunction with improved treatment has “led to substantial global progress” (Uplekar et al. 2013, p. 1248), passive case finding is thought to be incapable of detecting cases early enough to sufficiently reduce TB incidence (WHO 2013; see also Golub et al. 2005; Golub & Dowdy 2013; Uplekar et al. 2013). The problem for health planners is that wide-scale use of active case finding remains beyond the resources of most developing countries – South Africa included – and so passive case finding will continue to be the primary method of case detection for the foreseeable future. “Those are the resources that we don’t have, and will probably never have”, district manager Dr Van Zyl remarked.

While the government clinics did not possess these resources themselves, however, all TB cases that were identified during the trials were immediately referred to them, including their names, addresses and contact details. In my conversations with the clinic staff, they often compared and critiqued their own passive case finding strategies with SATVI’s capacity to conduct active case finding amongst their participants. The impression I got from the nurses and support staff was that the kind of individuals SATVI were referring over to them were those that they might not otherwise have seen – or at least, until a much later stage. For example, I was talking to the TB room clerk at Worcester CDC about the kinds of day-to-day knowledge sharing that SATVI and the government clinics engaged in:

JD: So would you call it an exchange of data then?

R: You could say that because they actually found the people. Sometimes

they did find the people and people that we ordinarily would not have found.

Some patients we wouldn't have found back in the areas where we don't have a far-reaching...we can only reach the people closest to us.

JD: People that come into the shores.

R: Ja. It's difficult for us to go actually outside and actively search for patients. So in a way they do give us data. Not the data that they do research on, but the basic data: the patient has got TB, this is his name and his surname, and then that is the address and you should follow up on him.

For this TB clerk, SATVI had a greater 'reach' than the government clinics into community settings, and as a result they would often have TB cases on their radar that the clinics might not have otherwise, along with the "basic data" that would enable to follow up on the patients. A similar response came from Nurse Botha of De Doorns clinic's TB room when I asked him whether he thought that SATVI and the clinics had a "complementary relationship" with one another:

JD: Would you say that it's a complementary relationship with SATVI?

R: I think it's a good thing because sometimes we don't reach all of the patients. And they will come and they will send a little baby, or they will come and say that they tested this child and he must go and do the screening there.

Sister May of Empilisweni's TB room, meanwhile, observed that SATVI's staff did visits to Worcester's schools to conduct a variety of screenings and follow-ups, something which she stated was beyond the scope of the resources of the government clinics:

JD: Do you ever find it's almost more work for you?

R: Like they go to the schools. We don't go to the schools. So they check the

children, and they find children of people that are supposed to be starting on TB treatment or ARVs or follow-ups. So they're doing a good job.

When the clinic staff were reflecting upon the benefits of SATVI's active case finding techniques, they were certainly concerned with the health of the patients themselves. However, from an epidemiological perspective there was also the infection factor: the longer patients remained undiagnosed, the more likely they were to spread the disease. Some of the clinic staff took this more distanced perspective and noted the advantage of SATVI's active community presence upon infection rates. Sister Harmse of Empilisweni's TB room, for instance, said to me that: "They pick up cases of TB and send them to us – we've had about three or four since October. They're a very committed team. They pick up cases that are out there in the community, which is good because then they don't infect everyone".

Paediatric TB is less threatening from a public health perspective than TB in other age groups "because it is usually smear-negative and is thus considered to make a relatively minor contribution to the spread of TB" (WHO 2007, p. iv). However, TB is even more of a threat to infants than others: children under two years of age tend to be the least symptomatic and yet are at the highest risk of developing severe TB, including TB meningitis (WHO 2007; Hatherill et al. 2010; Bynum 2012). Dr Gilbert, Brewelskloof's paediatrician, was therefore highly appreciative that streams of infants were brought within his reach by during SATVI's infant trials:

For their outcomes, it was good. We picked up some children that were so sick and weren't at the clinic, but were sent here [the CV ward] first time, with active TB, so sick that I couldn't send them home for their TB treatment. They must be admitted here [Brewelskloof]. Fresh from the street.



Whilst severe cases of TB were far from uncommon, as Dr Gilbert suggests, the aggregate effect of active case finding across study cohorts was that the kind of TB picked up tended to be mild and early stage. This might be contrasted with what was happening outside of the trial environment, where, because of the subtlety of symptoms and limited access to healthcare, cases tended to be picked up at a more advanced stage. In other words, the chances of survival were higher through being part of a trial. District manager Dr Van Zyl went so far as to say that SATVI, by identifying TB during vaccine trials, was making a “significant public health contribution”.

Speaking to both research and clinic staff, I also began to get a sense of the difficult social situations that could be encountered as infants and their mothers came to the trial site after TB was suspected and how tricky these were to handle. Nurse Botha of De Doorns clinic recounted one incident where they had a child who they wanted to send for X-rays with suspected TB. This child was also a trial participant, and in fact SATVI wanted to expedite the process to ensure the child was diagnosed as soon as possible. What struck me was the emphasis that Nurse Botha placed upon the mother’s motivations for taking the child to SATVI, given that she had missed several clinic appointments:

I did have a patient, a mom with her child, and the child was supposed to go for X-Rays. But that child was in the study. So, they asked if they could come and get the patient and take the patient to X-Rays – but earlier. There is like a...we help each other...That mother, when she goes to SATVI they give her money. So maybe she was like that, because she didn’t come on our dates.

She thought we wouldn’t give her money, so she’s not going to go.

Study coordinator Dayna further explained what happened when this mother brought the child to SATVI’s site:

She demanded the money while doing the procedure [gastric lavage]. I said, no, it doesn't work like that, I must first complete the procedure and then I can give you the money. Can you just go on a little bit? And she was very abusive to us...And one of the CRWs got agitated with her: "ja, you must go and buy milk for the child, and you must go and do this with the money for the child". And I intervened and I said, you know what, we have no right at all to tell her what she must do with the money. If she feels she wants to do whatever with the money, that is up to her. We have no right. It is her child, remember, we can't take responsibility for her child. This is her child. Please, do not tell her to go and buy milk and food for the child.

The, she went to the X-ray department where the hospital's social worker came into contact with her and summoned her for a dressing down:

Then she went to see the social worker because she was actually intoxicated when she brought the child here. The Brewelskloof social worker picked that up when she went to the X-ray department, so she wanted to see this participant...And [the social worker] said, "you know what, it's very irresponsible to do that".

What we can see through this incident is not only a darker side of the social world within which TB finds traction to that depicted in Chapters 6 and 7. It also highlights the difficult position of those who face situations like the above and the ambiguities of whose responsibility it is to intervene. Dayna's position, consistent with the way in which SATVI frames participants – as responsible, autonomous individuals – was that it was not the institute's place. Only the state social worker was deemed have the authority to intervene in the situation. However, such disinterestedness was not easy for the

fieldworkers, who assumed the mother was planning to spend the money on more alcohol and thus, out of concern for the baby, wanted to convey the importance of spending it on milk. Being in a position to intervene but not having the authority to do so was a difficult thing to accept for many of SATVI's staff, and the line was often crossed in response to challenging situations.

### **Post-Referral Management of Patients**

We have begun to see a conception of SATVI's entanglement in primary healthcare provision in which participants, often motivated by money, were subjected to active surveillance technologies and made visible to the state the moment that TB (or otherwise) was identified, thus extending their reach into community settings. The assumption so far, however, is that participants, upon being diagnosed promptly took the referral letters to the clinics for treatment. Many, if not most, did exactly this. As Liz, one of SATVI's nurses, observed: "Most of them really did go. Because if you go there [the clinic] a day or two later and you're looking for more participants, you will ask, 'did so and so come?', and the sister said 'yes'". However, it was a far from uncommon occurrence that participants did not attend, particularly when the diagnosis entailed exclusion from the study, which was the case for TB. In this section, I show the kinds of interactions and allocations of responsibility that occurred between SATVI and government clinic staff – especially those who worked together previously in the clinics – in these instances where participants seemed to be more resistant to undergoing the transition from participant to patient.

Perhaps not by coincidence, it tended to be those among SATVI's nurses who had previously worked in the government clinics who had the least trust in participants that they would attend the clinics and could cite the most examples to support this. As we saw earlier, study coordinator Monique said that she was very careful to make sure that they

did not “carry” participants (or the mothers of infant participants) so as to “make them responsible” if a diagnosis was made. However, she in fact had a highly sceptical view of what participants did with the referral letters:

We give them a letter, because the monitor will ask for proof. But TB participants will throw that letter in the bin. Ignorance, I think. It happened a lot with our babies, dying of TB, after being discharged from the CV ward with five days of TB treatment. And then when that treatment is done, after five days, the mother played innocent. Quite a few of them. Quite, a few of them.

Similar stories were true of adults and adolescents too. Their beliefs as to why they did not attend the clinics varied. Monique above cited “ignorance”. However, one of the most commonly cited reasons was that there was a difference between a diagnosis made at SATVI and at a government clinic. The majority of instances in which TB was diagnosed in a government clinic was when the individual was so sick that they were actively looking for treatment. Participants diagnosed at SATVI, by contrast, were not necessarily seeking medical attention for a sickness, especially once they had passed screening, had been vaccinated and were involved in the follow-up stages. In the previous chapter, we saw that being part of a vaccine trial could mean a lot to people and even be a life-changing experience. Then, all of a sudden, they were handed a TB diagnosis, often at such an early stage that they were not even feeling especially unwell, were excluded from the trial and had to brave the much-maligned government clinic system. In this sense, there was a ‘gap’ between diagnosis and treatment that was not only institutional but also of a different social substance to when people were diagnosed in a clinic.

Who was responsible for ensuring that participants bridged the ‘gap’? SATVI’s responsibility for following up on clinic referrals depended substantially upon the

condition diagnosed and whether or not it entailed exclusion. In terms of TB, which in vaccine trials entailed exclusion, SATVI were required by protocol to continue following up their participants for a period of time post-diagnosis. In the case of infant trials (such as the trial of MVA85A), infants with TB were followed up until the end of the trial like all others. But for adult trials, the protocols were often more vaguely worded, involving a shorter period of follow-up to check that they had started and were continuing with treatment. While they do check, however, SATVI were not *responsible* for ensuring treatment compliance. Sovereign responsibility theoretically resided solely with the government clinics. Yet it became clear that, when it actually came to concrete instances of participants not attending their clinic, SATVI's nurses, particularly those who had previously worked in the government clinics, frequently felt compelled to step over the 'line' between where their formal responsibility ended and where that of the clinics began.

To see why, it is worth reminding ourselves of what life was like for the TB room nurses. Confined behind the walls of the clinics, they were swamped with seemingly endless streams of patients, often irritated because of the thankless challenge of steering several hundred individuals through a long course of antibiotics. A referral letter faxed through from SATVI did not mean much if the patient did not actually show up in person – it was “faceless”, as Sister du Plessis put it – and their ability to chase these elusive individuals up was contingent upon the limited powers of the home-based carers (see Chapter 4). Well aware that of this situation, SATVI's nurses felt wholly responsible for making sure that this “faceless” participant was placed in front of a TB nurse by using their mobility in community settings to locate the individual in question. This usually involved liaising with the clinics to confirm they could be seen that day. For instance, I asked Dayna how often she drew upon her informal contacts in the clinics and the purposes for which she used them:

Yes, a lot! Especially with their problem patients and our problem patients. If we know that this is a problem patient, especially with the HIV story and TB patients that doesn't take his medication. "I have a patient here, please can you see him today, because this is a runner". I will tell [Sister du Plessis] this is a difficult person, you don't get him, I managed to track him down, can you squeeze him in?" She will say "yes I can squeeze him in".

Note the kind of language used here: "problem patient" (rather than 'responsible' participant), "runner" (rather than compliant health-seeker) and "track him down" (rather than letting him go to the clinic of his own volition). This was, indeed, the same language used by the government clinic nurses themselves that we saw in Chapter 4, especially in their more exasperated moments. It struck me that, when managing participants who violated the abstract imagining of the SATVI-clinic referral relationship and thus triggered the governmental stereotype of the irresponsible TB patient, research nurses partially reverted back to their roles as agents of the state, taking on the responsibility for ensuring that participants commenced treatment beyond that which was legitimate as a distanced researcher. It was nurses who just happened to be in different institutional settings, one group with command over resources appropriated from research to further the common end of ensuring that patients started their TB treatment. Sovereign responsibility was thus extended over the research context in moments of public health urgency.

Importantly, this feeling of mutual responsibility was shared by the government clinic staff themselves. For they felt able to contact SATVI for help if there was a patient who they were having problems locating in the community – even, in fact, when they were not a participant. The facility manager of Worcester CDC, for instance, perceived SATVI as a resource that they could "use": "We can even use them. If you need

something you can just tell them, okay, bring that patient”. Moreover, they were conscious that SATVI’s fleet of vehicles and superior access to hard-to-reach community settings made them more effective than the home-based carers at locating and bringing in resistant patients. Sister du Plessis, for example, compared the institute with the carers:

They [SATVI] go to the house and say, listen what is the problem? And then they bring the patient here. They’ve got transport and they bring them. Sometimes the DOTS workers here, the normal DOTS workers, they [the NGO] tell them that they mustn’t drive the patients. They are not allowed to drive the patients. If you ask [the NGO coordinator], will you please get the patient and bring him, then they say they are not supposed to...where SATVI on the other hand they drive the patients here. So, if he must begin, he will begin.

When SATVI got involved in the situation, therefore, there was a greater confidence that participants would successfully begin treatment.

Interestingly, one of the most important advances in the government clinic functioning has partially undermined SATVI’s ability to streamline ‘difficult’ participants to the TB rooms. As noted in the previous chapter. Worcester CDC and, subsequently, the other clinics in which I conducted fieldwork, moved from a system where people queued to receive attention that day to an appointment system. In this new system, depending upon the severity of the condition one would be given appointment on a subsequent day. Dayna, however, suggested that this often made it very difficult, which she described using the example of an HIV-exposed infant:

I had this baby. And I found that this baby never had the immunisations. So, I phoned the clinic and I said, listen here, I know this is a runaway mother. I

referred the mother, the mother was there, but they said “no we can’t see you, we will see you on another day”. So she never want back. And then later on, we got the mother again [with the car] and we went and made her sit at the clinic, and they said again “no we can’t see you today”. Only at twelve weeks, I *pushed* my way into this system and I said, please see this child! So they did, but now this child has been without Nevirapine for six weeks, and then, at the end of the day, this child seroconverted to HIV.

With the stakes being so high, Dayna took it upon herself to speak to one of the primary healthcare managers and tried to assert that SATVI were here to “complement” the clinics and that, with the caveat that it would not be an everyday occurrence, be allowed in “problem” cases to jump the queues. In such cases, as she put it, “we can meet each other somewhere in the middle”. Here there is a contest in sovereign responsibility at the juncture of two competing imperatives: that of improving the delivery of healthcare for many thousands, versus the heightened responsibility felt towards a much smaller minority of participants in a clinical trial. This is characteristic of the uneven distribution of resources in clinics affected by high-end clinical trials. Nonetheless, it raises questions of equity and fairness on the part those who were sitting in the lines that would be bypassed by SATVI’s participants (see Angweni et al. 2015). Indeed, from the perspective of someone waiting patiently in line, one might even feel more resentful given that those seen to be skipping the queues were ones who seemingly did not even want to be there.

## Conclusion

This chapter has completed our exploration of the movement of people through SATVI’s trials by focusing on the point at which many were diagnosed with TB or another medical



condition and were referred to a government clinic for treatment. Focusing on the status transition from ‘participant’ to ‘patient’, I highlighted the ambiguities, complementarities and tensions that straddled the border between research and care. At the institutional level, the division of responsibilities was clear: participants might have acquired the status of ‘universal’ human subjects in the game of ‘global’ scientific research, but the state remained participants’ rightful healthcare provider (Barsdorf et al. 2010). This division was supported wholeheartedly by the research team, especially the nurses who had been trained to respect the stringent hierarchies of the health system.

Yet no amount of deference or humility could entirely obscure the ways in which SATVI stepped over into the work of TB control and primary healthcare provision through the ground-level conduct of its vaccine trials. At times, SATVI was perceived to have *overstepped* its authority by the government clinic staff (Angweni et al. 2015). But what little resentment the clinic staff harboured was outweighed by the valuable contribution SATVI was seen to make to their day-to-day work lives. For SATVI’s superior mobility, capacity for active case finding and even their ‘hold’ over Worcester’s poor (primarily through money) functioned to extend the reach of the clinics into hard-to-reach community settings, enabling them to exert greater control and influence in the areas where TB holds greatest traction. In fact, SATVI’s trials partially fulfilled the nostalgic sense of longing for the degree of community presence and control that had been largely stripped from the government clinics since the end of apartheid (see Chapter 4).

Yet at the same time, questions and contestations over sovereign responsibility emerged in the process of connecting participants to healthcare, especially in the occurrence that participants seemed more resistant to making the transition from ‘participant’ to ‘patient’. Who was responsible, for what and for how long? The line had

to be continuously managed, by nurses in particular, who had to juggle their sense of responsibility for participants with their valuable contacts and allegiances with the clinics. For the most part, SATVI and government clinic staff found ways to collaborate in order to bridge the ‘gap’ engendered by the research environment between diagnosis and treatment. However, it was not always straightforward, with the imperatives of providing healthcare for the majority running into tension with the concentrated responsibility felt towards individuals in trials. This chapter thus contributes towards our understandings of ‘collaborative partnerships’ in global health and how responsibility is allocated and enacted on the ground.

While the focus this chapter and Chapter 7 are not identical, they offer two different and competing narratives of what and who is to blame for the current state of the TB epidemic and SATVI’s emergent healthcare role in relation. From one perspective, SATVI appears as a ‘first point of care’ of sorts for citizens who feel that they have been wronged by their government. From another, the institute appears as a high-resource agent of surveillance and control, extending the reach of the state into the TB ‘hotspots’ and the elusive bodies contained therein. As I mentioned in the introduction to this chapter, it is not my position that either version is ‘correct’ or closer to the ‘truth’. Rather, the fact that SATVI manifests so differently depending upon the perspective testifies to just how messy and divisive the TB epidemic. Moreover, it highlights power of TB discourse to shift blame away from the structural determinants of disease and on to impoverished individuals. These two versions of SATVI’s emergent healthcare role reflect the proverbial angel and devil that sit on the shoulders of Worcester’s impoverished coloured residents and the perpetual struggle between them that this thesis has sought to capture. As Jenson (2008, p. 8) puts this, the struggle between people’s “everyday sense of being themselves as persons who live normal and moral lives on the

one hand, and on the other the colouredness, sustained by the full gamut of stereotypical framing and definition”.

# Conclusion

## Rethinking Carina's Choice

This thesis opened with the story of Carina and the 'brave choice' that she made to enrol her baby into one of SATVI's TB vaccine trials. The comic provided a good device to begin my thesis because it encapsulated many aspects of the socioeconomic, epidemiological and cultural context that we encountered in the preceding chapters. This includes poverty, unemployment, a huge burden of infectious disease (especially TB), gangsterism, a heavy reliance upon under-resourced government healthcare facilities and a strained relationship between the clinics and the residents that they serve. The comic also reveals the way in which 'global' science and ethics imagines the relationship between SATVI and its study community. This relationship is one in which SATVI's staff might be an active presence in the Breede Valley – driving around, recruiting and monitoring trial participants, and occasionally making appearances in government facilities – but all the while neutral, distanced observers, representing but not intervening upon the local situation.

The chapters set out to describe, firstly, the TB epidemic – its magnitude, challenges and discursive framings – into which SATVI's trials have been inserted. Secondly, they sought to show how SATVI's trials have become entangled in the Breede Valley's socioeconomic and healthcare landscape through the ground-level conduct of its TB vaccine trials. I have thus attempted to view the significance of the trials in people's lives not simply as providing access to scarce resources for bare survival in the new biopolitical order of global health (Geissler et al. 2008; Rottenburg 2009; Kamuya et al. 2014; Nguyen 2011, 2015). Rather, I have tried to bring into view a broader a more fine-grained appreciation of the spectrum of roles, imperatives and subject positions with

which people in Africa approach, interpret and appropriate clinical trials. In particular, building upon a number of insightful ethnographic studies conducted in Cape Town, I show that SATVI has been creatively read into people's attempts to craft lives that they consider to be valuable, moral and respectable in conditions that have been rendered extremely precarious by centuries of racialised domination, exclusionary policies and stereotyping (Salo 2003; Jensen 2008; F. Ross 2010, 2015). In order to reiterate and reflect upon the findings in the preceding chapters, this conclusion revisits some of the scenes from *Carina's Choice* in order to show how far we have come from the depiction of medical research with which this thesis opened. Using the comic, I divide my reflections into four sections: 'TB, Gangsters and Nurses'; 'Carina's Brave Choice'; 'From Misconceptions to Moral Economy'; and 'The Limits of Hope'. The final section offers directions for future ethnographic research both with SATVI and in the broader field of TB-related science.

### **TB, Gangsters and Nurses**

The Kleynhans family – comprised of Carina, Cookie, Tupac, Veronica and Vernon – experiences some of the challenges associated with impoverished living that hardened into the stereotype of the 'coloured problem family' during the colonial and apartheid regimes (Jensen 2008). Vernon is unemployed; the family possess very little money; Cookie's father is nowhere to be seen; and Tupac is vulnerable to entering a gang if he has not already. Jensen (2008) argues that a central figure in 'coloured' townships is that of the *skollie* (thug), which is ambiguous in the sense that he both undermines positive identities and is the figure against which people stake their own claims to morality and respectability. Accordingly, the central character in *Carina's Choice* for our purposes is arguably not Carina but rather Tupac.

Jensen's insightful analysis, however, does not extend so far as the landscape of health seeking and delivery, which is one reason that Tupac's cough and his visit to the clinic is especially revealing. At first, there is hesitancy in the house to recognise TB as a possibility, and Vernon's strong response to suggestion hints at the stigma surrounding the disease and people's hesitancy to attend a clinic to be diagnosed. More significantly, at the clinic Tupac is uncooperative with the uniformed government nurse, and in one telling image (below) he is facing away from her, arms folded in defiance, while the nurse stands with hands on her hips, berating him. As we saw in Chapter 4, this captures the way that government clinic staff viewed the challenges of the TB epidemic. That is, people appear to be unresponsive to the new post-apartheid governmentality premised upon 'patient responsibility' (Compion 2008) and as a result there is a 'gap' between the clinic and home, with a feeling of little control or influence in low-income suburbs where the disease continues to spread unabated.



It is for this reason that I have introduced the ‘problem TB patient’, a figure overlapping with but not identical to the *skollie*. The problem patient is engendered by the ways in which TB discourse and the language of ‘patient responsibility’ focuses attention upon individual behaviour while deflecting attention away from structural determinants of disease (Farmer 2000; Compion 2008; Harper 2006; Harper 2010). He is, perhaps most vividly, captured in the flyer composed by Sister du Plessis (Chapter 4, p. 99). Yet, as we saw in Chapter 6, the problem TB patient is further moralised and reified in the popular imagination, closely associated with notions of ‘dirt’ – not only dirty places but also dirty *people* and dirty *practices*, including smoking, alcoholism and drug abuse (Abney 2011). I have suggested that this stereotypical figure features prominently in the ways that people frame themselves as ‘responsible’ health seekers as well as moral and respectable individuals more generally.

The context into which SATVI’s trials have been inserted is therefore a complex, unstable and divided post-apartheid setting in which TB is far more than a brute fact. From the perspective of the government clinics, SATVI has ‘locked in’ to precisely the low-income, gangster-ridden community settings that they struggle so much to exert control any control over. From the perspective of residents themselves, the institute has become entwined in people’s attempts to craft ordinary, respectable lives on the peripheries of social and economic life, in the mist of and often in response to *skollies*, ‘problem patients’ and the ‘dirty’ lifestyles with which they are both associated. To characterise the everyday hardships in which TB is entwined, I have tentatively use the term ‘abjection’, the starting point in the useful schema around which a number of the chapters (5, 6 and 7) were constructed empirically to make sense of the meaning and significance of SATVI’s trials in people’s lives. That is, the movement from *abject* to *object* to *subject* (Simpson & Sariola 2013).

### Carina's 'Brave Choice'

While Tupac is in the consultation room with the nurse, Carina is approached by Mandisa – one of SATVI's fieldworkers – who introduces the institute and the trial for which they are currently recruiting (below). Carina's lack of familiarity with SATVI's work reflects the way that ethical guidelines construe clinical trials as isolated events that take place between predetermined enrolment and end points, rather than as cumulative and embedded in people's collective memories (Geissler et al. 2008; Kelly 2011; Geissler & Molyneux 2011). In reality, as this thesis has shown, it is actually harder to find people who are *not* familiar with SATVI's work, given the volume and variety of vaccine trials that have been conducted since 2001. "SATVI – something for all the family" was how one researcher jokingly expressed the fact one can find entire families – such as the Kleynhans' – who have been involved in the institute's research in one form or another over the last fifteen years.





After having the trial explained to her, Carina is asked to make a ‘brave choice’ to enrol Cookie into the trial for the ‘greater good’ of a new TB vaccine. Now the language of choice, and its close relationship with the bioethical ideal of autonomy, has arguably been the primary sticking point for anthropological critique. This is because of its associations with neoliberalism in healthcare (Fisher 2009) and, in particular, the way it deflects attention away from the relations of inequality between researchers and study populations and reduces what is ‘ethical’ to clear communication, participant rights and minimising the possibility of ‘undue inducement’ (Geissler et al. 2008; Petryna 2009; Kingori 2013). This thesis has offered a different take on the language of ‘choice’, ‘autonomy’ and ‘greater good’. In Chapter 3, we saw that considerable work went into building the capacity and conditions for the social relations of research against the backdrop of a deeply entrenched culture of medical paternalism. Yet the inverted power relationship between researchers and participants brought about by the trial environment was interpreted largely positively by both participants and staff (cf. Sariola & Simpson 2011). Chapter 5 showed how SATVI’s fieldworkers saw their roles in the trials as important because they were able to make people feel valued, included and capable of doing something good, which takes on particular significance given peoples’ fears of being considered *weggooi mense* (throw-away people). Chapter 7, moreover, argued that one of the most important reasons why SATVI was valued as a health space was that they felt they were treated with respect, as equals and as being included in decision-making process in contrast to the perceived indignities, stereotyping and authoritarianism of the government clinics.

Drawing attention to the positive uptake of the ideal of the autonomous, choosing human subject around which research relations gravitate is not to suggest that it is a universal, nor that it has a fixed or stable referent. In fact, it is precisely because it was a

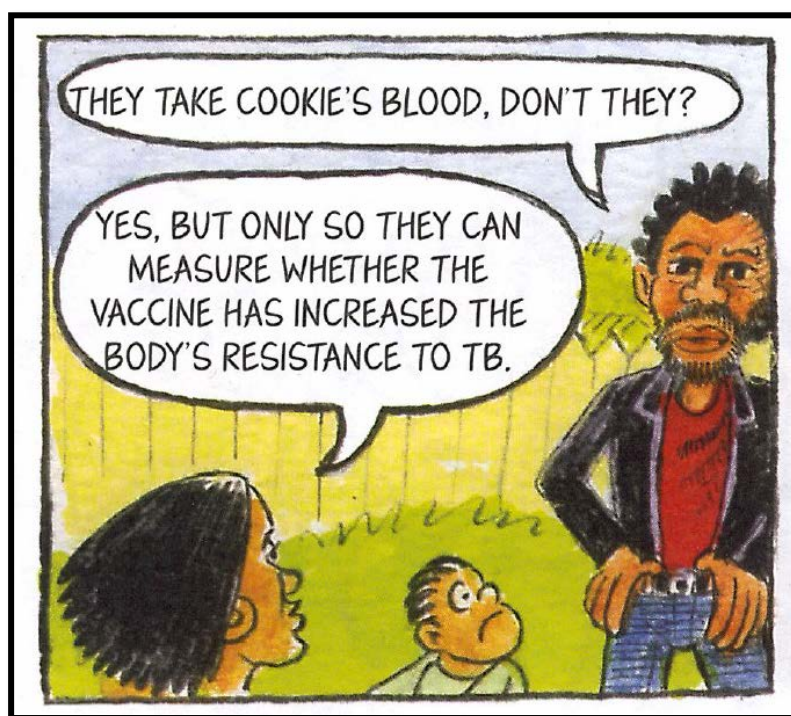
novelty for many to be treated as such that it had tangible *effects*, the positivity of which becomes appreciable in light of how they arrived into the category of ‘universal’ human subject from a position as abjects-cum-objects. In the rush to show what the neoliberal language of ‘autonomy’ and ‘choice’ obscures (Fisher 2007; Mol 2008), we easily lose sight of what it might mean to be treated as autonomous, moral and altruistic in conditions that strip away the possibilities for self-worth. Whether or not this was an attainable reality is a matter that is discussed further on.

### **From Misconceptions to Moral Economy**

Bioethics, as mentioned above, tends to assume that the category of the human subject is universal and fixed. But within the more dialogical relationship engendered by the research environment, both participants and research staff were bringing their own values, beliefs and ideas of proper personhood to bear on what it meant to be a human subject and how this subjectivity was connected to the science. Chapters 5 and 6 in particular suggested that, in the same moment that trials protocols were shaping participants as measurable and commensurable objects, for those on the ground the all-important site of knowledge and intervention was the subject, the moral agent – even the soul. It is for this reason that the moral dimensions of TB – especially its symbolic associations with ‘dirt’ and ‘dirty practices’ – were not stripped away by the trial protocols. Rather, they were refracted through and indeed amplified by the trials’ everyday practices and routines, as people projected their self-perceptions and moral aspirations onto the category of the human subject.

The way that many participants interpreted the science and their roles in it as participants are easily placed into the bioethical category of ‘misconception’, which brings us to the final scene in *Carina’s Choice*. At Cookie’s first birthday party, a man voices his suspicions about SATVI’s work (below). He firstly suggests that the study

vaccines might actually give people TB and, secondly, questions the purposes to which SATVI are putting Cookie's blood (Leach, Fairhead & Small 2006). But these are quickly dismissed as 'misconceptions' by the better-informed people at the party, and in the end the man comes to see he was mistaken. While I did not encounter too many suspicions in interviews, blood nonetheless featured prominently in people's understandings, with many people expressing their participation in terms of donations of 'clean blood'. Chapter 6 argued that the idiom of clean blood should not be viewed as a mere misconception but rather as a tangible, symbolically rich interpretation that is grounded in the day-to-day rhythms of the trials and people's highly-moralised understandings of TB. Blurring the distinction between object and subject, it defies the passive disposition to sickness that makes them scientifically valuable from a bio-scientific perspective, reflecting the desire to be set *apart from* rather than *representative of* a 'high-burden' community. In some cases, participation could catalyse drastic transformations in outlook and lifestyle, with profound social effects beyond the confines of the trials (Brives 2013).



Observing a vaccine trial run by British MRC in The Gambia, Geissler and colleagues (2008) argued that the moral economy of truth and objectivity prized by science had to coexist with another on the ground, involving “material contact and substantial transactions, notably of blood and medicine”. The sharp resistance beyond the requirements of trial protocols to practices and lifestyles considered to be ‘dirty’ points towards a different kind moral economy surrounding trial participation. This moral economy incorporates values such as respectability, cleanliness, ‘good’ lifestyles and responsibility and can be seen as partially defined in opposition to the symbolic associations between TB and ‘dirt’. It is no less situated than the moral economy identified by Geissler and colleagues. But it does, I believe, draw our attention beyond the material dimensions of trial participation to a broader spectrum of imperatives and subject positions with which people approach and attribute significance to clinical research. Insofar as this thesis can be read as a critique of bioethics, it is therefore not a critique of ‘autonomy’ and the language of ‘choice’. Rather, given the creativity and dynamism with which people read SATVI’s trials into their day-to-day lives, this thesis critiques the equally problematic category of ‘vulnerability’ that is applied to varying degrees to almost all SATVI’s participants.

Vulnerability, then, has been treated not as an a priori category referencing ‘compromised autonomy’, but rather as emergent in practices: experienced, interpreted and acted upon in ways not always visible from the abstract perspective of bioethics. In the preceding chapters, we saw a variety of ways in which people felt profoundly vulnerable: the effects of chronic poverty, disempowerment and racial stereotyping, the threat of gang life and violence, the fear of alcoholism, and drug addiction, and the perceived indignities of interactions with the state. Whereas bioethicists tend to see the principle issues of human subject research as turning on ‘autonomy’, one thing that

emerges strongly here is that SATVI is actually one of the only places many people felt safe, dignified and respected. The institution was creatively used to avoid certain vulnerabilities. It was used as a platform to confront others. But the notion of vulnerability as it is used in bioethics tends to frame people as passive, docile and obliging, rather than as dynamic, driven and critical individuals navigating complex sociomedical spaces (Chambers 1989; Levine et al. 2004; K. Brown 2015). The common phrase, “it’s not about the money, it’s about...”, pointed towards an array of canny ways in which people were interpreted and using the trials, for instance Leighton, who viewed participation as an opportunity for personal growth and transformation amidst instability and unpredictability (Chapter 6).

Chapter 6 inverted the question of vulnerability and turned it back on the trials themselves. It asked: if people start transforming their lifestyles in tandem with becoming trial participants, could it alter their chances of getting TB and threaten the possibility of proving vaccine efficacy? The point of this question is not to challenge the science but simply to highlight that people are dynamic, unpredictable and harder to force a frame over than the image of vulnerability suggests. Whilst SATVI’s trials are striving towards the future good of a new TB vaccine, people are not sitting still in the meantime; they have their own hopes and aspirations and use these trials to help further them in ways that ethnography is ideally suited to capture.

### **The Limits of Hope**

Whilst I have attempted to capture the creativity with which people in impoverished environments build lives that they consider to be valuable, moral and respectable, I have also kept in view the tensions, contradictions and often futility of these world-building efforts. Moreover, I have attempted to do so in a context where life is often desperately cruel and unpredictable. Both Jensen (2008) and Ross (2015) draw attention to the

“positive imaginative horizons” (F. Ross 2015, p. S99) that the notion of *ordentlikheid* provides, it contains the very structures of dominance that made it available as an emic category. In the same way that Jensen (2008) showed that people framed themselves respectability by projecting the *skollie* elsewhere and on to others, there was something sad about the way in which participants set their own motives against an imagined majority who were perceived as only there ‘for money’ and often to fuel practices that were associated with the *skollie* or ‘problem TB patient’. While such practices are a reality in post-apartheid Worcester, I concur with Jensen’s analysis that there is a sense in which people were pointing fingers at their own stereotype, reinforcing the very relations of inequality that they sought to escape.

People’s highly-moralised understandings of TB and the way that these deflect attention away from structural determinants (Farmer 2000; Harper 2006; Harper 2010; Abney 2011) also set people up for perceived ‘failure’. At the end of Chapter 6, we saw hints at people who dropped out of SATVI’s trials. What is especially troubling is that, if they were indeed excluded from the trials, then it was certainly not because they had done anything ‘wrong’, and yet they appeared to have interpreted the exclusion as a personal moral failing, that is, reverting to ‘dirty’ lifestyles. They might not even have been excluded at all but simply too ashamed to return. The moral triage enacted by the trials, while emancipatory for some, was a source of dejection for others. Moreover, despite people’s self-perceptions as responsible health seekers, a TB diagnosis is a daunting prospect. It is, moreover, perhaps even more of a struggle to accept given that one moment they felt they were a part of something good and where they felt valued and respected, and the next they were handed a TB diagnosis, excluded and had to attend a place that was perceived as quite the opposite. It was uncanny how quickly the governmental stereotype of uncaring, irresponsible bodies resurfaced the moment that people did not

attend the clinics for treatment and the approach to patients that were legitimised in moments of public health urgency. As Jenson (2008) might argue, ‘defaulting’ was almost the default mode in the governmental imagining and was poised and waiting to (re)surface.

The way that participants were interpreting and acting upon SATVI’s trials reflects the way in which people are looking outside of usual and especially state-affiliated institutions for hope and positive horizons. Yet, most of this was happening beyond the visibility of the state and, in fact, from the perspective of the government clinic nurses, SATVI took on a very different appearance. There was a degree of frustration that, in the same moment SATVI had such ‘hold’ over Worcester’s residents – which was attributed to the R150 ‘reimbursements’ – they had such a struggle retaining patients. Nonetheless, SATVI was perceived by clinic nurses as an ally to the state in controlling TB, extending their reach into hard-to-reach, dangerous community settings and control over the elusive, often ‘irresponsible’ people living therein (Chapter 8). As I suggested in Chapters 4 and 8, it is not my position that the perspectives of the government nurses are ‘wrong’, ‘ignorant’ or belie a lack of ‘care’. But their perspectives do show how difficult it is, in the everyday frustration and exhaustion of providing healthcare to many thousands of people, to keep in view the structural violence that underpins people’s apparent ‘irresponsibility’. It is my hope that this thesis, by highlighting the ways in which the TB epidemic is differentially experienced by healthcare professionals and residents, will be useful for health authorities as they strive to provide a health service that is legitimate and workable in a country still grappling with the enduring legacies of apartheid.

## Shifting Markets and Future Research

The way that I have described SATVI's research programme in this thesis might give the impression of a stable and constant stream of TB vaccine research. But the reality is, markets in TB-related medical research are changing and in ways that do not favour SATVI's particular area of expertise. Fewer efficacy trials are being funded, due in part to the realisation that vaccines such as that trialled by SATVI between 2009 and 2012 can show such promise in early-phase testing and yet still 'fail' when tested on large study cohorts. Needing to keep its doors open, SATVI is beginning to run *drug* trials to "fill the void", as one doctor put it. On the one hand, this is not nearly as fulfilling for SATVI's researchers, whose expertise is in TB vaccines and they have historically had a large role in the design of the trials. On the other, it has been suggested that SATVI's niche in years to come might be *therapeutic vaccines*. That is, vaccines that are administered as part of treatment regimens to shorten the treatment process. In this regard, drug trials and related studies might be thought of as 'capacity building' for therapeutic vaccine trials as research conducted in the formative years was capacity building for efficacy trials (Chapter 3).

One question that emerges from an anthropological perspective is: what will the move towards involving patients with active TB do to perceptions of SATVI's work in the Breede Valley? As we have seen, SATVI has developed a reputation as working with healthy people and, more specifically, as being in the business of 'clean blood'. Not only does this mean SATVI participation is not stigmatised but, in fact, as I have shown, the institute has become a place associated with moral, respectable personhood, which was defined in opposition to associations between TB and 'dirt'. So, what happens when SATVI start involving TB patients? What will this mean for the government clinics now that the institute is stepping even further into work that is usually their domain? How will research staff engage with the issue of 'defaulting' on medication? Will they hold patients

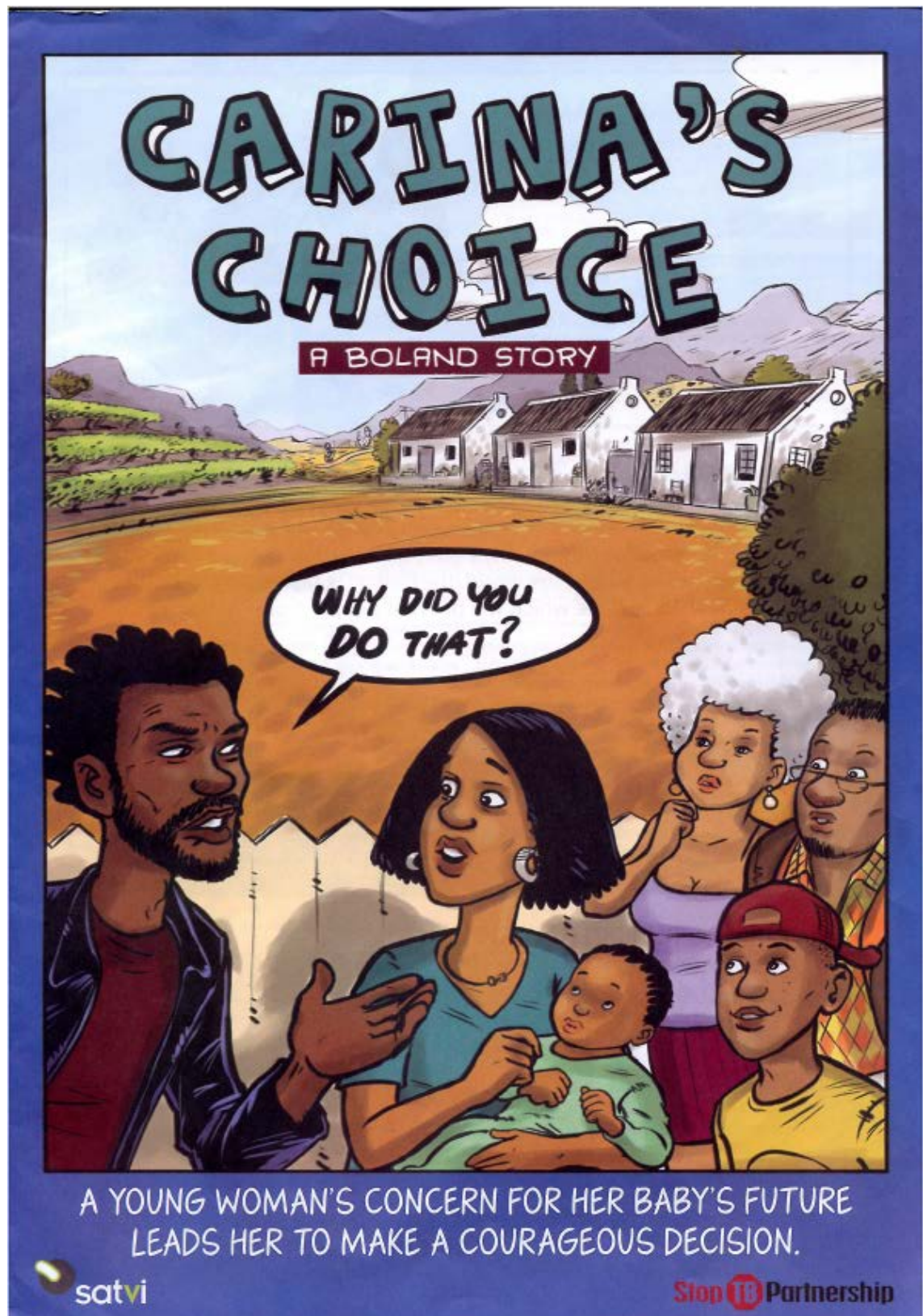


accountable and be stern with them? SATVI's shifting identity and the way that it is experienced and interpreted at different levels by the multitude of stakeholders in the institute's research opens up novel and important possibilities for anthropological investigation.

Looking further outwards, SATVI is one of several large research institutes conducting both TB vaccine and TB drug trials in South Africa. Many of these trials are in fact multi-sited trials, with the same protocols being implemented in often very different sociocultural and epidemiological contexts. Originally, I planned my PhD research as being multi-sited, planning in particular to 'follow' a large adult early efficacy trial through South Africa, in particular the trial that I have referred to as the Adult Efficacy Trial. It was decided that this was beyond the scope of a PhD, and I have certainly not regretted the depth of analysis that has been enabled by my exclusive focus on SATVI. But in order to build further upon my research, a possible next step is to shift the level of analysis outwards to incorporate a number of sites, for instance regarding the similarities and differences in community perceptions of these research institutes. How is the research of these other institutes received by those involved in their ground-level conduct? How are the same or similar protocols implemented differently across different regional contexts? While anthropology has historically been associated with deep immersion in a single, bounded field site, today multi-sited ethnography is widely practiced because of the increasingly multi-sited nature of the social phenomena being explored (Marcus 1995). Shedding light upon the social fabric and ethical implications of TB-related trials arguably means looking towards these broader networks of activity in South Africa and across the developing world as they cross both spatial boundaries and levels of scale.

# Appendix 1

## Carina's Choice



## THE KLEYNHANS FAMILY

The Kleynhans family live in a small town in the Boland. The father, Vernon (44), was until recently employed as a supervisor in a fruit processing business, but has been retrenched.

The mother, Vanessa (42), does voluntary work at a local pre-primary school.

Carina (22), has an 18 month-old baby called Venetia, but everybody calls her Cookie. Cookie's father is nowhere to be seen.

Trevor (14), known by the nickname Tupac, is in Grade 10 but is having discipline problems at school. He belongs to a 'crew' of teenage boys who prefer to bunk school and hang out listening to rap music and getting up to mischief. Lately, Tupac has developed a bad cough that won't go away.



Carina & Cookie    Tupac    Vanessa    Vernon

## WHY THIS COMIC?



TB is a big problem worldwide, especially here in the Boland community. Like communities around the world, the Boland is taking part in studies to find a new TB vaccine which will prevent people from getting TB.

Researchers need the support of the community. Our communities need to understand what clinical research is. You must participate in studies freely, on an informed basis, and with a full understanding of what will happen when you take part, what is required of you when you take part in a study and your rights.

The comic aims to communicate information in an entertaining and understandable way. Through the comic we want to inform our participants and the community about TB vaccine clinical research. It is being produced in Afrikaans, Xhosa and English.

It is the responsibility of us as researchers to make sure that you are aware and kept informed. This includes communications through various means, especially through the Community Advisory Board, radios and newspapers and reading material such as this comic.

If you would like to give us feedback on the comic, feel free to contact us at 023 346 5400 or email Linda Rhoda at [linda.rhoda@uct.ac.za](mailto:linda.rhoda@uct.ac.za).

## THIS COMIC IS DEDICATED TO YOU

Without the support of the Boland, our TB vaccine clinical research is not possible.

This comic is dedicated to everyone who is helping SATVI find a new, more effective TB vaccine - our community, our Community Advisory Board, our local and international partners, **and most importantly, our study participants...**

## WE WISH TO THANK...

- the SATVI Community Advisory Board
- the drama students and educators of Worcester Senior Secondary School
- the moms in our baby study
- our SATVI colleagues
- the Global Partnership to Stop TB, for funding of this comic

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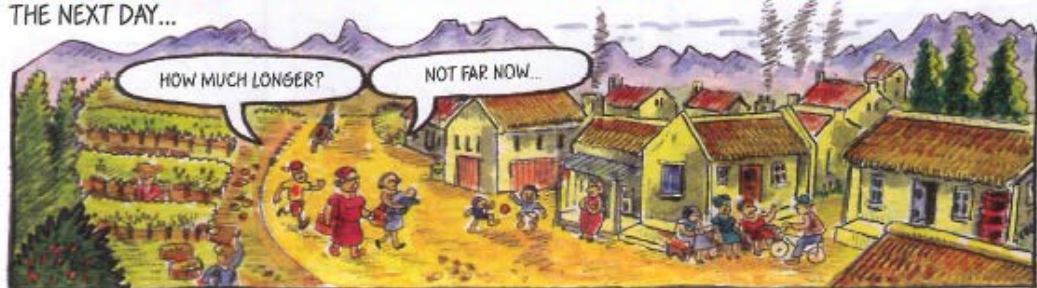








THE NEXT DAY...













DO YOU ALL KNOW HOW VACCINES WORK?

NOT REALLY... NO SORT OF...

WE INJECT THE VACCINE INTO THE BODY...

... SO THAT THE BODY'S IMMUNE SYSTEM CAN BUILD UP A RESISTANCE TO THE DISEASE...

IF TB GERMS EVER ATTACK THE BODY AFTER THAT, THE IMMUNE CELLS WILL BE THERE TO DESTROY THEM!

ISN'T IT DANGEROUS TO DO THAT? I MEAN, TO A BABY?

NO, NOT AT ALL.

ALL VACCINES ARE FIRST TESTED ON PEOPLE. WE CALL THESE CLINICAL TRIALS OR RESEARCH. THERE ARE STRICT RULES TO PROTECT PARTICIPANTS. THAT'S WHY WE DO RESEARCH IN PHASES OR STAGES.

WE START WITH JUST A FEW PEOPLE. WITH EACH NEW PHASE OF THE TRIAL, THE GROUP GETS BIGGER.

PHASES OF RESEARCH		
PHASE ONE	PHASE TWO	PHASE THREE
SMALL GROUP OF UP TO 20 PEOPLE	BIGGER GROUPS OF 60 TO 1000	THOUSANDS OF PARTICIPANTS

AT THE MOMENT SATVI IS BUSY WITH A VERY BIG TRIAL FOR A NEW VACCINE. THE TRIAL INVOLVES THOUSANDS OF BABIES.

NOT DIRECTLY, BUT ONE DAY, WHEN SHE HAS CHILDREN OF HER OWN...

WILL COOKIE BE ABLE TO BENEFIT FROM THIS VACCINE?

...THEY WILL BE PROTECTED BY THE NEW VACCINE.

GAGA!

WOULD YOU AND COOKIE LIKE TO HELP US?

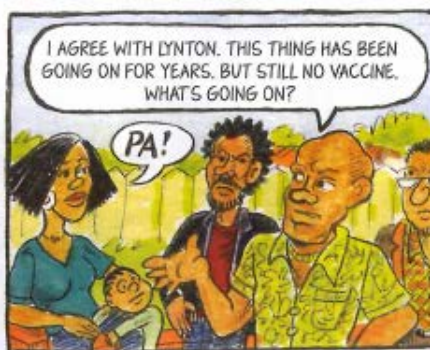
HELP YOU? HOW?

YOU COULD VOLUNTEER COOKIE TO PARTICIPATE IN THE TRIAL.

WOW!

8









## Appendix 2

### The Rhythms of Study Visits

Each of the vaccine trials being run at the time of my fieldwork had their own social dynamics. These were influenced by a range of factors, including the layout of the vaccine clinic, the age range of the study cohort and the size of the trial. Nonetheless, the trial protocols entailed similar routines. Below I provide an overview of the trial protocols, from screening, to vaccination, to the follow-up process.

#### Screening

The screening visit, which would determine whether people were eligible be enrolled, occurred shortly after informed consent had been obtained by a fieldworker at their homes. On a day that was convenient for them, they were picked up from their homes by one of SATVI's drivers, and were taken to the trial site at Brewelskloof Hospital and to the vaccine clinic where the trial for which they were being screening was being run. The screening process involved a wide variety of medical questions, tests and examinations. Observations such as height and weight could be taken by fieldworkers wherever there was space, often in the corridors. Everything else was performed behind closed doors, the bulk of which was performed by a nurse.

The nurse took their blood pressure and temperature, questioned them for any TB-related symptoms and asked a standardised series of questions regarding medical history. One of SATVI's study doctors then followed up on this medical information and also conducted a physical examination. Back with the nurse, blood from a finger prick was taken for an HIV test (pre- and post-test counselling was conducted by a fieldworker), before further blood was drawn for a quantiFERON (TB infection) test and to check for liver and kidney function. People were also asked to produce a measure of sputum to

check for active TB. All the while, people were informed of what was happening, asked whether they were still happy to take part, and given the opportunity to ask questions. Finally, they received a R150 ‘reimbursement’ and were driven home again by logistics.

For many people, screening was their first and last involvement in the trials. Screening failures were particularly high in trials – such as the Adolescent Trial study and the Adult Safety Trial – where TB-uninfected people were required. But any number of issues that precluded enrolment could emerge during screening. HIV-positive results were in the minority, but not uncommon. BMI, blood pressure, TB history – almost any concurrent medical condition – might also lead to exclusion depending upon the particular criteria of the trial in question. It was not usually until at least a week later, when all blood and sputum samples had been analysed in the lab, that people would hear definitively (usually by phone but via home visit if needs be) whether they were eligible to be enrolled into the study. For those found to have something that required medical attention, they were referred to their usual healthcare provider for further diagnostics and potential treatment.

## **Vaccination**

Those who passed screening were invited back to SATVI for enrolment and vaccination. Again, people would be asked whether they were happy to proceed, if they had any questions and finally, after some final medical checks, injected with either the study vaccine or a placebo. Immediately following vaccination, they were kept at the site for a minimum of two hours for observation. If they experienced any adverse events, they received immediate medical attention by SATVI’s trial team and, if necessary, they would be admitted to Worcester Hospital. Provided they did not experience any adverse events at the vaccination visit, participants were driven home again.

**Follow-up**

From the moment of injection, the long process of evaluating the safety and/or efficacy of the study vaccine began. Provided they did not experience any adverse events (AEs) at the vaccination visit, participants were driven home again, but would return frequently for ('reimbursed') follow-up visits, typically at days 7, 28, 84, and every other 84 days until the end of the trial (approx. 20 visits in total).

For safety evaluations, participants were asked to self-monitor at home and make a note of any observations in a diary. In addition, as with prior visits, participants were informed what was happening, asked whether they had any questions, and if they would like to continue. Then they underwent a series of questions, tests, and examinations, often but not always including blood draws. Medical issues would frequently emerge during the follow-up process, which may or may not have led to exclusion, and referral to their healthcare provider where necessary. In efficacy trials (e.g. the Adult Efficacy Trial), SATVI were particularly vigilant for signs of active TB disease, because a certain number of cases were expected – even desired – in order to show that the study vaccine works.

# Appendix 3

## Socioeconomic Indicators and Social Grants

### Socioeconomic indicators – South Africa

**Poverty** 53% of people in South Africa lived below the poverty line in 2011, as defined by R779 per person per month. <sup>36,37</sup>

**Unemployment** 26.5% in January 2017. <sup>38</sup>

### Socioeconomic indicators – Breede Valley Municipality<sup>39</sup>

Total Population (2015)	174,198
Total Households (2015)	46, 963
Per Capita Income (2011)	R25, 923
High School Pass Rate (2014)	82.1%

In 2011:

- 13.7% of households (or 6004 households) lived on less than R400 per month (£23) – which is considerably less than the poverty line
- 17% of households live on less than R800 per month (£47) – which is around the poverty line per EACH person)
- 32% lived on less than R1,630 per month (£96).

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<sup>36</sup> Statistics South Africa (2014)

<sup>37</sup> Although in an independent analysis, (Budlender et al. 2015) suggest that the 2011 figure should be 63% because they think that the poverty line ought to be defined as R1042 per person per month. See also: <http://theconversation.com/how-current-measures-underestimate-the-level-of-poverty-in-south-africa-46704>

<sup>38</sup> Statistics South Africa (2017)

<sup>39</sup> Western Cape Government (2015)

**Social Grants<sup>40</sup>**

<b>Grant</b>	<b>Rand / month</b>	<b>Notes</b>
Child Support Grant	380	[per child] To receive this grant, you must be the primary caregiver of a child. The child must be under the age of 18 years old
Foster Child Grant	920	[per foster child]
Care Dependency Grant	1,600	[per child] Care dependency grant offers help to full-time caregivers of a child / children with disabilities
Old-Age Pension	1,600	[per pensioner] over 60 years
	1,620	[per pensioner] over 75 years

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<sup>40</sup> Source: <https://www.westerncape.gov.za/general-publication/applying-social-welfare-grant>



## **Appendix 4**

### **Informed Consent Forms**

- (1) Clinical Trial Participant Information Sheet and Consent Form
- (2) SATVI Staff Information Sheet and Consent Form
- (3) Healthcare Professional Information Sheet and Consent Form

## **(1) Clinical Trial Participants - Participant Information Sheet**

My name is Justin Dixon. I am a student from the University of Durham in the United Kingdom. I am seeking your help with a study I am doing about SATVI's work in the Cape Winelands East district. Please take time to read the following information carefully, and take time to consider whether you want to take part in this study or not. Please ask me if there is anything that is unclear to you, or if you would like more information about the study before making your decision.

### **■ What is the purpose of this study?**

In this study, I would like to find out about how SATVI helps to improve people's health in the district by researching new vaccines, working with local healthcare centres, and improving awareness of TB. This study will last for 12 months, based at SATVI's field project office in Worcester Approximately 135 people, with a variety of ties to SATVI's work, will be invited to take part in total. The study will help SATVI to improve its relationship with the community. It will also help to make medical research more beneficial to people in South Africa.

### **■ If you agree to participate, what will you be asked to do?**

I am asking you to take part in my study because you have some knowledge or experience of SATVI's work in the Cape Winelands East district. I would like you to take part in a single interview with me at SATVI's office. During the interview I will ask you about your knowledge and experiences of SATVI's work, about TB, and also about healthcare in your community. This will take between 30 and 50 minutes of your time. I will ask your permission to tape record the interview. I will use the information you share with me during the interview to describe SATVI's work in articles and reports.

### **■ Voluntary participation**

Please understand that it is your choice whether to take part or not. There will be no penalty if you decide not to take part, and this will not affect your relationship with SATVI in any way. If you agree to take part now, you can choose to interrupt or end your participation at any point.

### **■ Are there any risks or benefits if I take part?**

The questions I ask you are unlikely to cause you any harm or distress. However, if any of the questions asked make you feel uncomfortable in any way, you do not have to answer them, and I will move on to the next question. In addition, in the unlikely event that the need arises, I can refer you to a counselling service for further support about the topics raised by in the interview. There are no direct benefits for participating in my study. However, you might value the opportunity to discuss your knowledge and experiences of SATVI's work. In addition, your input will be beneficial in the long run for the community and others affected by medical research in South Africa.

### **■ Confidentiality**

In order to make sure that the information you share with me is as confidential as possible, the tape recording of your interview will be destroyed once I have written the interview down. Also, whenever I use any of the information you share with me during the interview, I will not mention your name or any other features that might identify you

personally. These conditions will only be broken in the event of an emergency, where there is a risk to you or to another person.

■ **Further information**

If you have any concerns or questions regarding this study that have not been answered, please feel free to contact me:

Justin Dixon  
Anthropology PhD Student  
Phone: 076 516 1489  
Email: [justin.dixon@durham.ac.uk](mailto:justin.dixon@durham.ac.uk)

or

Michele Tameris  
Clinical Researcher  
Phone: (023) 346 5400  
Email: [michele.tameris@uct.ac.za](mailto:michele.tameris@uct.ac.za)

The full title of the study is “Beyond Protocol: Ethics, Experimentation and Healthcare at a Tuberculosis Vaccine Clinical Trial Site in Rural South Africa”. This study has been approved by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee, and the University of Durham Department of Anthropology Ethics Committee. If you would like to find out more about your rights as a research participant, please call: (021) 406 6492.

## Clinical Trial Participants - Informed Consent Form for Interview

This form is to show that you have understood what it will mean to help me with this study and are happy for me to use information shared during the interview.

Signing the form will mean that you have agreed to participate in the study entitled “Protocol and Beyond: Ethics, Experimentation and Healthcare during Tuberculosis Vaccine Trials in South Africa”.

This means that:

- The research project has been explained to me and I have had the chance to ask questions.
- I voluntarily agree to take part in the study.
- I understand that at **any time** during the interview, I am free to interrupt or end my participation without penalty.
- I understand that my decision whether or not to take part in an interview will not harm my relationship with SATVI.
- I understand that information shared during this interview may be used in articles and reports, and I agree to the information being used in this way.
- I understand that my name and identifying features will not be revealed.
- If the interview is tape recorded, I understand that the tape recording will be destroyed once it has been written down.

Print name of study participant: \_\_\_\_\_

Signature of study participant: \_\_\_\_\_

Date: \_\_\_\_\_

Print name of person taking consent: \_\_\_\_\_

Signature of person taking consent: \_\_\_\_\_

Date: \_\_\_\_\_

In the event that the participant is **under 18 years of age**:

Print name of consenting parent/legal guardian: \_\_\_\_\_

Signature of consent of parent/legal guardian: \_\_\_\_\_

Date: \_\_\_\_\_

## **(2) SATVI Staff - Participant Information Sheet**

My name is Justin Dixon and I am a researcher from the University of Durham in the United Kingdom. I am seeking your help with a study I am doing about SATVI's work in the Cape Winelands East district. Please take time to read the following information carefully, and take time to consider whether you want to take part in this study or not. Please ask me if there is anything that is unclear to you, or if you would like more information about the study before making your decision.

### **■ What is the purpose of this study?**

In this study, I would like to find out about how SATVI helps to improve people's health in the district by researching new vaccines, working with local healthcare centres, and improving awareness of TB. This study will last for 12 months, based at SATVI's field project office in Worcester. Approximately 135 people, with a variety of ties to SATVI's work, will be invited to take part in total. The study will help SATVI to improve its relationship with the community. It will also help to make medical research more beneficial to people in South Africa.

### **■ If You Agree to Participate, What will the Study Involve?**

As someone with an important role within SATVI, I would be thrilled if you agree to be an ongoing participant in my study. If you agree to take part, I will arrange times with you to spend time with you as you go about your day-to-day work in order to learn more about what you do and about your role within SATVI. To aid my memory I will take field notes during this time. I would also like you to take part in a small number of interviews with me over the course of the year about your work at SATVI and about TB and healthcare in the community. If you agree to be interviewed, I will ask your permission to tape record and transcribe our conversations. Finally, I will hold some meetings with a small number of SATVI's staff sitting together [a focus group] to discuss SATVI's work. I would be grateful if you would agree to take part in one or more of these during the study. I will use the information shared throughout the year to describe SATVI's activities in academic articles and other reports.

### **■ Voluntary Participation**

Please understand that it is your choice whether to take part in my study or not, and there will be no penalty if you decide not to, and this decision will not affect your job at SATVI in any way. Due to the in-depth nature of this study, I will be especially careful to ensure that you are comfortable with my presence at all times, and that you do not feel that my study is intruding upon your privacy. If there are any aspects of my study that you do not wish to take part in, this is perfectly acceptable.

### **■ Are there any risks or benefits if I take part?**

Your participation in my study is unlikely to cause you any harm or distress. However, if any part of the study begins to make you feel uncomfortable in any way, you are welcome to interrupt or end your participation at any point. During the study, it is likely that I will ask you quite a lot of questions, particularly during interviews and focus groups. You do not have to answer any of these that make you feel uncomfortable or that you do not wish

to answer. In addition, in the unlikely event that the need arises, I can refer you to a counselling service for further support about the issues raised by the study. There are no direct benefits for participating in this study. However, you might value the opportunity to share your knowledge and experiences of SATVI's work. In addition, your input will be beneficial in the long run for SATVI staff, the community, and others involved in medical research in South Africa.

### ■ Confidentiality

Assuring that the information you share as a participant remains as confidential as possible is a key priority. To this end, unless you explicitly ask me to, I will not discuss any of the information you share with me during the project with SATVI's management staff. Recorded interview and focus group discussions will be destroyed once the recording has been transcribed. In addition, your name and any identifying characteristics will not be included in any data or in any academic articles and reports arising from this study. Where you share information with me in public spaces I will also do my utmost to ensure that conversations are not overheard. In addition, I will encourage those who take part in focus groups to respect the confidentiality of information shared during these sessions. Confidentiality will only be breached in exceptional circumstances in the event of risk to yourself or third parties.

### ■ Further Information

If you have any concerns or questions regarding this study that have not been answered, please feel free to contact me:

Justin Dixon  
Anthropology PhD Student  
Phone: 076 516 1489  
Email: [justin.dixon@durham.ac.uk](mailto:justin.dixon@durham.ac.uk)

or

Michele Tameris  
Clinical Researcher  
Phone: (023) 346 5400  
Email: [michele.tameris@uct.ac.za](mailto:michele.tameris@uct.ac.za)

The full title of the research project is Beyond: Ethics, Experimentation and Healthcare during Tuberculosis Vaccine Trials in South Africa. The protocol has been reviewed and approved by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee and in the United Kingdom by the University of Durham Department of Anthropology Ethics Committee. If you would like to find out more about your rights as a research participant, please call: (021) 406 6492.

## SATVI Staff - Informed Consent Form

The purpose of this form is to show that you have understood what it will mean to help me in this study and to allow me to use data collected from your involvement. Signing the form will mean that you have agreed to participate in the study entitled “Protocol and Beyond: Ethics, Experimentation and Healthcare during Tuberculosis Vaccine Trials in South Africa”.

This means that:

- The research project has been explained to me and I have had an opportunity to ask questions.
- I certify that I am at least 18 years of age.
- I voluntarily agree to participate in the study.
- I understand that at any time during the course of the research, I am free to interrupt or end my participation without penalty.
- I understand that this study will last 12 months.
- I understand that this research involves ongoing observation of everyday practices and events.
- I understand that my decision whether or not to participate will not jeopardise my future relations with SATVI.
- I understand that my name and identifying features will not be revealed in any data or any articles and reports.
- I understand that recorded information will be destroyed once it has been transcribed.

Print name of study participant: \_\_\_\_\_

Signature of study participant: \_\_\_\_\_

Date: \_\_\_\_\_

Print name of person taking consent: \_\_\_\_\_

Signature of person taking consent: \_\_\_\_\_

Date: \_\_\_\_\_

## (3) Healthcare Professional - Participant Information Sheet

My name is Justin Dixon and I am a researcher from the University of Durham in the United Kingdom. I am seeking your help with a study I am doing about SATVI's work in the Cape Winelands East district. Please take time to read the following information carefully, and take time to consider whether you want to take part in this study or not. Please ask me if there is anything that is unclear to you, or if you would like more information about the study before making your decision.

### ■ What is the purpose of this study?

In this study, I would like to find out about how SATVI helps to improve people's health in the district by researching new vaccines, working with local healthcare centres, and improving awareness of TB. This study will last for 12 months, based at SATVI's field project office in Worcester. Approximately 135 people, with a variety of ties to SATVI's work, will be invited to take part in total. The study will help SATVI to improve its relationship with the community. It will also help to make medical research more beneficial to people in South Africa.

### ■ If You Agree to Participate, What will the Study Involve?

I have asked you to take part in my study because your work as a healthcare professional in Cape Winelands East is related to SATVI's research on TB vaccines in the district. If you agree to take part, I will spend time with you as you go about your day-to-day work in order to learn more about healthcare in Cape Winelands East and its relationship to SATVI's research. To aid my memory I will take field notes. I would also like to interview you about your knowledge and experiences of SATVI's research, as well as about TB and healthcare in the district. If you agree to be interviewed, I will ask your permission to tape record and transcribe the proceedings. The length of your involvement in the study will depend upon how long you – and other participants – are comfortable with my presence at your place of work, and could be staggered over a number of time periods. I will use the information shared during this time to describe SATVI's activities in academic articles and other reports.

### ■ Voluntary Participation

Please understand that it is your choice whether to take part in my study or not, and there will be no penalty if you decide not to. Due to the in-depth nature of this study, I will be especially careful to ensure that you are comfortable with my presence at all times, and that you do not feel that my study is intruding upon your privacy. If you wish to participate in one but not both of the above research activities, this is also perfectly acceptable.

### ■ Are there any risks or benefits if I take part?

Your participation in my study is unlikely to cause you any harm or distress. However, if any part of the study begins to make you feel uncomfortable in any way, you are welcome to interrupt or end your participation at any point. During the study, it is likely that I will ask you quite a lot of questions, particularly during interviews. You do not have to answer any of these that make you feel uncomfortable or that you do not wish to answer for any reason. In the unlikely event that the need arises, I can also refer you to a counselling service for further support about issues raised by the study. There are no direct benefits for participating in my study. However, you might value the opportunity to discuss your knowledge of SATVI's work and healthcare in the district. In addition, your input will be beneficial in the long run for the community and others affected by medical research in South Africa.



### ■ Confidentiality

Assuring that the information you share as a participant remains as confidential as possible is a key priority. Recorded interview discussions will be destroyed once the recording has been transcribed. In addition, your name and any identifying characteristics will not be included in any data or in any publications and reports arising from this research. Where you share information with me in public spaces I will also do my utmost to ensure that conversations are not overheard. Confidentiality will only be breached in exceptional circumstances in the event of risk to yourself or third parties.

### ■ Further Information

If you have any concerns or questions regarding this study that have not been answered, please feel free to contact me:

Justin Dixon  
 Anthropology PhD Student  
 Phone: 076 516 1489  
 Email: [justin.dixon@durham.ac.uk](mailto:justin.dixon@durham.ac.uk)

or

Michele Tameris  
 Clinical Researcher  
 Phone: (023) 346 5400  
 Email: [michele.tameris@uct.ac.za](mailto:michele.tameris@uct.ac.za)

The full title of the research project is Beyond: Ethics, Experimentation and Healthcare during Tuberculosis Vaccine Trials in South Africa. The protocol has been reviewed and approved by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee and in the United Kingdom by the University of Durham Department of Anthropology Ethics Committee. If you would like to find out more about your rights as a research participant, please call: (021) 406 6492.

## Healthcare Professional - Informed Consent Form

The purpose of this form is to show that you have understood what it will mean to help me in this study and to allow me to use data collected from your involvement.

Signing the form will mean that you have agreed to participate in the study entitled “Protocol and Beyond: Ethics, Experimentation and Healthcare during Tuberculosis Vaccine Trials in South Africa”.

This means that:

- The research project and my participation have been explained to me and I have had an opportunity to ask questions.
- I certify that I am at least 18 years of age.
- I voluntarily agree to participate in the study.
- I understand that at **any time** during the course of the research, I am free to interrupt or end my participation without penalty.
- I understand that this research involves ongoing observation of everyday practices and events.
- I understand that my decision whether or not to participate will not harm my future relations with SATVI.
- I understand that my name and identifying features will not be revealed in any data or any articles and reports.
- I understand that recorded information will be destroyed once it has been transcribed.

Print name of study participant: \_\_\_\_\_

Signature of study participant: \_\_\_\_\_

Date: \_\_\_\_\_

Print name of person taking consent: \_\_\_\_\_

Signature of person taking consent: \_\_\_\_\_

Date: \_\_\_\_\_

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